JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
(Established by Act No.30 of 2008)
Kukatpally, Hyderabad–500085, Telangana State (India)

Academic Regulations of M.Pharm. (Regular/Full Time) Programmes, 2022-23 (R22)
(CBCS)
(Effective for the students admitted into I year from the Academic Year 2022-23 and onwards)

1.0 **Post-Graduate Degree Programmes in Pharmacy (PGP in Pharmacy)** Jawaharlal Nehru Technological University Hyderabad (JNTUH) offers **Two** Years (**Four** Semesters) full-time Master of Pharmacy (M.Pharm.) Degree programmes, under Choice Based Credit System (CBCS) at its constituent (non-autonomous) and affiliated colleges in different specializations.

2.0 **Eligibility for Admissions**

2.1 Admission to the PGPs shall be made subject to eligibility, qualification and specializations prescribed by the University from time to time, for each specialization under each M.Pharm. programme.

2.2 Admission to the post graduate programme shall be made on the basis of either the merit rank or Percentile obtained by the qualified student in the relevant qualifying GPAT Examination/ the merit rank obtained by the qualified student in an entrance test conducted by Telangana State Government (PGECET) for M.Pharm. programmes / an entrance test conducted by JNTUH/ on the basis of any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.3 The medium of instructions for all PG Programmes will be **ENGLISH** only.

3.0 **M.Pharm. Programme (PGP in Pharmacy) Structure**

3.1 The M.Pharm. Programmes in Pharmacy of JNTUH are of Semester pattern, with **Four** Semesters consisting of **Two** academic years, each academic year having **Two** Semesters (First/Odd and Second/Even Semesters). Each Semester shall be of 23 weeks duration (inclusive of Examinations), with a minimum of **100** instructional days per Semester.

3.2 The student shall not take more than **four** academic years to fulfill all the academic requirements for the award of M.Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M.Pharm. programme.

3.3 **UGC/PCI** specified definitions/descriptions are adopted appropriately for various terms and abbreviations used in these PG academic regulations, as listed below:

3.3.1 **Semester Scheme**

Each Semester shall have 'Continuous Internal Evaluation (CIE)' and 'Semester End Examination (SEE)'. Choice Based Credit System (CBCS) and Credit Based Semester System (CBSS) are taken as 'references' for the present set of Regulations. The terms 'SUBJECT' and 'COURSE' imply the same meaning here and refer to 'Theory Subject', or 'Lab Course', or 'Design Subject', or 'Mini Project with Seminar', or 'Dissertation', as the case may be.

3.3.2 **Credit Courses**

All subjects/courses are to be registered by the student in a semester to earn credits which shall be assigned to each subject/course in an L: T: P: C (Lecture Periods: Tutorial Periods: Practical Periods:

Credits) structure based on the following general pattern:

- One credit for one hour/week/semester for theory/lecture (L) courses
- One credit for two hours/ week/semester for laboratory/ practical (P) courses or tutorials (T)

Other student activities like study tour, guest lecture, conference/workshop participations, technical paper presentations and mandatory courses (***Audit Courses***) will not carry any credits.

3.3.3 Subject Course Classification

All subjects/courses offered for the Post-Graduate Programme in Pharmacy (M.Pharm. Degree Programme) are broadly classified as follows. The University has followed in general the guidelines issued by UGC/PCI.

S.No.	Broad Course Classification	Course Group/ Category	Course Description
1	Core Courses (CoC)	PC- Professional Core	Includes subjects related to the Specialization in Pharmacy
		Dissertation	M.Pharm. Project or PG Project or Major Project
		Mini Project/ Seminar	Mini Project/Seminar based on core contents related to the Specialization in Pharmacy
2	Elective Courses (EIE)	PE - Professional Electives	Includes elective subjects related to the Specialization in Pharmacy
		OE - Open Electives	Elective subjects which include inter-disciplinary subjects or subjects in an area outside the Specialization in Pharmacy
3	***Mandatory Courses***	--	***Non-Credit Audit Courses***

4.0 Course Registration

4.1 A 'Faculty Advisor or Counselor' shall be assigned to each specialization, who will advise on the Post Graduate Programme (PGP), its Course Structure and Curriculum, Choice/Option for Subjects/ Courses, based on his competence, progress, pre-requisites and interest.

4.2 The Academic Section of the College invites 'Registration Forms' from students within 15 days from the commencement of class work through 'ON-LINE SUBMISSIONS', ensuring 'DATE and TIME Stamping'. The ON-LINE Registration Requests for any 'CURRENT SEMESTER' shall be completed BEFORE the commencement of SEEs (Semester End Examinations) of the 'PRECEDING SEMESTER'.

4.3 A Student can apply for ON-LINE Registration, ONLY AFTER obtaining the 'WRITTEN APPROVAL' from his Faculty Advisor, which should be submitted to the College Academic Section through the Head of Department (a copy of it being retained with Head of Department, Faculty Advisor and the Student).

4.4 If the Student submits ambiguous choices or multiple options or erroneous entries during ON-LINE Registration for the Subject(s) / Course(s) under a given/ specified Course Group/ Category as listed in the Course Structure, only the first mentioned Subject/ Course in that Category will be taken into consideration.

4.5 Subject/ Course Options exercised through ON-LINE Registration are final and CANNOT be changed, nor can they be inter-changed; further, alternate choices also will not be considered. However, if the Subject/ Course that has already been listed for Registration by the University in a Semester could not be offered due to unforeseen or unexpected reasons, then the Student will be allowed to have alternate choice either for a new Subject, if it is offered, or for another existing Subject (subject to availability of seats). Such alternate arrangements will be made by the Head of Department, with due notification and time-framed schedule, within the FIRST WEEK from the commencement of Class-work for that Semester.

5.0 Attendance Requirements

The programmes are offered based on a unit system with each subject being considered a unit. Attendance is calculated separately for each subject.

5.1 Attendance in all classes (Lectures/Laboratories) is compulsory. The minimum required attendance in each theory subject (***also mandatory audit courses***) including the attendance of mid-term examination / Laboratory etc. is **80%.** Two periods of attendance for each theory subject shall be considered, if the student appears for the mid-term examination of that subject. ***This attendance should also be included in the fortnightly upload of attendance to the University. The attendance of mandatory audit courses should be uploaded separately to the University.*** A student shall not be permitted to appear for the Semester End Examinations (SEE), if his attendance is less than **80%.**

5.2 A student's Seminar report and presentation on Mini Project shall be eligible for evaluation, only if he ensures a minimum of **80%** of his attendance in Seminar presentation classes on Mini Project during that Semester.

5.3 **Condoning of shortage of attendance** (between 70% and 80%) up to a maximum of 10% (considering the days of attendance in sports, games, NCC, NSS activities and Medical grounds) in each subject (Theory/Lab/Mini Project with Seminar) of a semester shall be granted by the College Academic Committee on genuine reasons.

5.4 A prescribed fee per subject shall be payable for condoning shortage of attendance after getting the approval of College Academic Committee for the same. The College Academic Committee shall maintain relevant documents along with the request from the student.

5.5 Shortage of Attendance below 70% in any subject shall in **no case be condoned.**

5.6 A Student, whose shortage of attendance is not condoned in any Subject(s) (Theory/Lab/Mini Project with Seminar) in any Semester, is considered as 'Detained in that Subject(s), and is not eligible to write Semester End Examination(s) of such Subject(s), (in case of Mini Project with Seminar, his/her Mini Project with Seminar Report or Presentation are not eligible for evaluation) in that Semester; and he/she has to seek re-registration for those Subject(s) in subsequent Semesters, and attend the same as and when offered.

5.7 A student fulfills the attendance requirement in the present semester, shall not be eligible for readmission into the same class.

5.8 **a)** A student shall put in a minimum required attendance in at least **three theory subjects (excluding *mandatory(audit)* course)** in first Year I semester for promotion to first Year II Semester.

b) A student shall put in a minimum required attendance in at least **three theory subjects (excluding *mandatory(audit)* course)** in first Year II semester for promotion to second Year I Semester.

6.0 Academic Requirements

The following academic requirements must be satisfied, in addition to the attendance requirements mentioned in item no. 5. The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks per subject / course (theory / practical), based on Internal Evaluation and Semester End Examination.

6.1 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to each subject/course, if he secures not less than **40%** of marks (**30** out of **75** marks) in the Semester End Examination, and a minimum of **50%** of marks in the sum total of CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together; in terms of Letter Grades and this implies securing **'D'** Grade or above in a subject.

6.2 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **Mini Project**, if student secures not less than **50%** marks (i.e. 50 out of 100 allotted marks). The student would be treated as failed, if student (i) does not submit a report on Mini Project or does not make a presentation of the same before the evaluation committee as per schedule or (ii) secures less than 50% marks in Mini Project evaluation. The failed student may reappear once for the above evaluation, as and when they are scheduled again; if the student fails in such 'one reappearance' evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

6.3 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **seminar & assignment**, if student secures not less than 50% marks i.e. 50 out of 100 allotted marks. **50** marks are allotted for **Seminar**, **50** marks are allotted for **Assignment, Total 50+50 = 100 marks**. The student would be treated as failed, if student (i) does not submit a report on seminar/does not submit the assignments as prescribed or does not make a seminar presentation before the evaluation committee as per schedule or (ii) secures less than 50% (i.e. < **25** marks out of **50**) marks in each of the seminar & assignment evaluations. The student failed in seminar evaluation may reappear once for it, as and when it is scheduled again; The student failed in assignment evaluation may submit the assignments once again for the evaluation, as and when the assignment submission is scheduled again. If the student fails in such 'one reappearance' evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

6.4 A student shall register for all subjects for total of **98** credits as specified and listed in the course structure for the chosen specialization, put in required the attendance and fulfill the academic requirements for securing **98** credits obtaining a minimum of **'D'** Grade or above in each subject, and all **98** credits securing Semester Grade Point Average **(SGPA) ≥ 6.0** (in each semester) and final Cumulative Grade Point Average **(CGPA)** (i.e., CGPA at the end of PGP**) ≥ 6.0**, and shall ***pass all the mandatory audit courses*** to complete the PGP successfully.

Note: (1) The SGPA will be computed and printed on the marks memo only if the candidate passes in all the subjects offered and gets minimum 'D' grade in all the subjects.

(2) CGPA is calculated only when the candidate passes in all the subjects offered in all the semesters

6.5 Marks and Letter Grades obtained in all those subjects covering the above specified **98** credits alone shall be considered for the calculation of final CGPA, which will be indicated in the Grade Card /Marks Memo of second year second semester.

6.6 If a student registers for extra subject(s) (in the parent specialization or other specializations of

Pharmacy) other than those listed subjects totaling to **98** credits as specified in the course structure, the performance in extra subject(s) (although evaluated and graded using the same procedure as that of the required **98** credits) will not be considered while calculating the SGPA and CGPA. For such extra subject(s) registered, percentage of marks and Letter Grade alone will be indicated in the Grade Card/Marks Memo, as a performance measure, subject to completion of the attendance and academic requirements as stated in items 5 and 6.1 - 6.4.

6.7 When a student is detained due to shortage of attendance in any subject(s) in any semester, no Grade allotment will be made for such subject(s). However, he is eligible for re-registration of such subject(s) in the subsequent semester(s), as and when next offered, with the academic regulations of the batch into which he is re-registered, by paying the prescribed fees per subject. In all these re-registration cases, the student shall have to secure a fresh set of internal marks and Semester End Examination marks for performance evaluation in such subject(s), and SGPA/CGPA calculations.

6.8 A student eligible to appear for the Semester End Examination in any subject, but absent from it or failed (failing to secure **'D'** Grade or above), may reappear for that subject at the supplementary examination as and when conducted. In such cases, his Internal Marks assessed earlier for that subject will be carried over, and added to the marks secured in the supplementary examination, for the purpose of evaluating his performance in that subject.

6.9 A Student who fails to earn **98** credits as per the specified course structure, and as indicated above, within **four** academic years from the date of commencement of his first year first semester, shall forfeit his seat in M.Pharm. programme and his admission **shall stand cancelled.**

7.0 Evaluation - Distribution and Weightage of Marks

The performance of a student in each semester shall be evaluated subject- wise (irrespective of credits assigned) for a maximum of 100 marks. The performance of a student in every theory subject/course will be evaluated for 100 marks, with 25 marks allotted for CIE (Continuous Internal Evaluation) and 75 marks for SEE (Semester End-Examination).

7.1 For theory subjects, 75 marks shall be awarded for the performance in the Semester End Examination and 25 marks shall be awarded for Continuous Internal Evaluation (CIE). The Continuous Internal Evaluation shall be made based on the average of the marks secured in the two Mid-Term Examinations conducted, first Mid-Term examinations in the middle of the Semester and second Mid-Term examinations during the last week of instruction. Each Mid-Term Examination shall be conducted for a total duration of 120 minutes with Part 'A' as compulsory consisting of 5 questions carrying 2 marks each (10 marks), and Part 'B' with 3 questions to be answered out of 5 questions, each question carrying 5 marks (15 marks). The details of the Question Paper pattern for Semester End Examination (Theory) are given below:

- The Semester End Examination will be conducted for 75 marks. It consists of two parts.

  i) Part A for 25 marks, ii) Part B for 50 marks.
- Part A is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
- Part B consists of 5 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

7.2 For practical subjects there shall be a Continuous Internal Evaluation (CIE) during the semester for 25 marks and 75 marks for semester end examination. Out of the 25 marks for internal evaluation:

1. A write-up on day-to-day experiment in the laboratory (in terms of aim, components/procedure, expected outcome) which shall be evaluated for 5 marks

2. 10 marks for viva-voce in the course concerned.
3. Internal practical examination conducted by the laboratory teacher concerned shall be evaluated for 10 marks.

The Semester End Examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University.

In the Semester End Examination held for 3 hours, total 75 marks are divided and allocated as shown below:

1. 10 marks for Synopsis
2. 50 marks for experiment
3. 15 marks for viva-voce on concerned laboratory course

A student has to secure 50 marks (i.e. 50% out of the 100 marks) allotted for CIE and SEE taken together.

7.3 There shall be Mini Project during I year II semester for **internal evaluation** of 100 marks. The Departmental Academic Committee (DAC) will review the progress of the mini project during the presentations and evaluate the same for 50 marks. Mini Project Viva Voce will be evaluated by the DAC for another 50 marks before the semester end examinations. Student shall carryout the mini project in consultation with the mini project supervisor which may include critically reviewing the literature, project implementation and submit it to the department in the form of a report and shall make an oral presentation before the DAC consisting of Head of the Department, Mini Project supervisor and two other senior faculty members of the department. The student has to secure a minimum of 50% of marks in i) mini project presentation and ii) mini project viva voce, to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.4 There shall be **seminar & assignment** during I Year I Semester & I Year II Semester for **internal evaluation** of **100** marks. **50** marks are allotted for **Seminar**, **50** marks are allotted for **Assignment, Total 50+50 = 100 marks**.

For **Seminar**, the student in consultation with the seminar supervisor shall collect the information on a specialized topic, prepare a report, and submit it to the department. The Departmental Academic Committee (DAC) consisting of Head of the Department, seminar supervisor and two other senior faculty members of the department will evaluate the seminar report for 50 marks before the semester end examinations. The student has to secure a minimum of 25 marks (i.e. 50% out of the 50 marks) allotted to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

For **Assignment**, the student is required to submit **one assignment from each theory subject/course** in I Year I Semester & I Year II Semester before the commencement of Semester End Examinations.

- In I Year I Semester there are 5 theory courses and 5 assignments are to be submitted in total, one assignment each to the concerned theory subject teacher. The concerned theory subject teacher will evaluate the assignment for 10 marks. So 5 assignments will be evaluated for 50 marks in total.

- In I Year II Semester there are 4 theory courses and 4 assignments are to be submitted in total, one assignment each to the concerned theory subject teacher. The concerned theory subject teacher will evaluate the assignment for 12.5 marks. So 4 assignments will be evaluated for 50 marks in total.

The student has to secure a minimum of 25 marks (i.e. 50% out of the 50 marks) allotted to be declared successful. If he fails to obtain the minimum marks, he may submit the assignments once again for the evaluation, as and when the assignment submission is scheduled again.

7.5 There shall be comprehensive viva-voce during II year I semester for **external evaluation** of 100 marks. It shall be evaluated by the committee consisting of an external examiner, Head of the Department, and two other senior faculty members of the department before the semester end examinations. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University. The student has to secure a minimum of 50 marks (i.e. 50% out of the 100 marks) allotted to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.6 Every candidate shall be required to submit a dissertation on a topic approved by the Dissertation Review Committee.

7.7 A Dissertation Review Committee (DRC) shall be constituted with the Head of the Department as Chairperson, Dissertation Supervisor and one senior faculty member of the Department offering the M.Pharm. programme.

7.8 Registration of Dissertation Work: A candidate is permitted to register for the Dissertation Work after satisfying the attendance requirement in all the subjects, both theory and laboratory.

7.9 After satisfying 7.8, a candidate must present in Dissertation Work Review - I, in consultation with his Dissertation Supervisor, the title, objective and plan of action of his Dissertation work to the Dissertation Review Committee (DRC) for approval within four weeks from the commencement of Second year First Semester. Only after obtaining the approval of the DRC can the student initiate the Dissertation work.

7.10 If a candidate wishes to change his supervisor or topic of the Dissertation, he can do so with the approval of the DRC. However, the DRC shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of Dissertation proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

7.11 A candidate shall submit his Dissertation progress report in two stages at least with a gap of **three** months between them.

7.12 The work on the Dissertation shall be initiated at the beginning of the II year and the duration of the Dissertation is two semesters. A candidate is permitted to submit Dissertation Thesis only after successful completion of all theory and practical courses with the approval of DRC not earlier than 40 weeks from the date of approval of the Dissertation work. For the approval of DRC the candidate shall submit the draft copy of thesis to the Head of the Department and make an oral presentation before the DRC.

7.13 The Dissertation Work Review - II in II Year I Sem. carries internal marks of 100. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate the work for the other 50 marks. The Supervisor and DRC will examine the Problem Definition, Objectives, Scope of Work, Methodology Adopted, Literature Survey in the same domain and progress of the Dissertation Work. A candidate has to secure a minimum of 50% of marks to be declared successful in Dissertation Work Review - II. If he fails to obtain the minimum required marks, he has to reappear for Dissertation Work Review - II as and when conducted.

7.14 The Dissertation Work Review - III in II Year II Sem. carries 100 internal marks. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The DRC will examine the overall progress of the Dissertation Work and decide whether or not the Dissertation is eligible for final submission. The evaluation shall be done as per the criteria given below:

Evaluation of Dissertation Book (Internal Evaluation):

Objective(s) of the work done	- 10 Marks
Methodology adopted	- 30 Marks
Results and Discussions	- 50 Marks
Conclusions and Outcomes	- 10 Marks
Total	- **100 Marks**

A candidate has to secure a minimum of 50% of marks to be declared successful in Dissertation Work Review - III. If he fails to obtain the required minimum marks, he has to reappear for Dissertation Work Review - III as and when conducted.

7.15 For Dissertation Evaluation (Viva Voce) in II Year II Sem. there are external marks of 100 and it is evaluated by the external examiner. The evaluation shall be done as per the criteria given below:

Evaluation of Presentation (External Evaluation):

Presentation of work	- 40 Marks
Communication skills	- 20 Marks
Viva-Voce	- 40 Marks
Total	- **100 Marks**

The candidate has to secure a minimum of 50% marks in Dissertation Evaluation (Viva-Voce) examination. If he fails to obtain the required minimum marks, he has to reappear for the same as and when conducted.

7.16 Dissertation Work Reviews - II and III shall be conducted in phase I (Regular) and Phase II (Supplementary). Phase II will be conducted only for unsuccessful students in Phase I. The unsuccessful students in Dissertation Work Review - II (Phase II) shall reappear for it at the time of Dissertation Work Review - III (Phase I). These students shall reappear for Dissertation Work Review - III in the next academic year at the time of Dissertation Work Review - II only after completion of Dissertation Work Review - II, and then Dissertation Work Review - III follows. The unsuccessful students in Dissertation Work Review - III (Phase II) shall reappear for Dissertation Work Review - III in the next academic year only at the time of Dissertation Work Review - II (Phase I).

7.17 After approval from the DRC, a soft copy of the thesis should be submitted for ANTI-PLAGIARISM check and the plagiarism report should be submitted to the University and be included in the final thesis. The Thesis will be accepted for submission, if the similarity index is less than **30%**. If the similarity index has more than the required percentage, the student is advised to modify accordingly and re-submit the soft copy of the thesis after one month. The maximum number of re-submissions of thesis after plagiarism check is limited to TWO. The candidate has to register for the Dissertation work and work for two semesters. After three attempts, the admission is liable to be cancelled. The college authorities are advised to make plagiarism check of every soft copy of theses before submissions.

7.18 Three copies of the Dissertation Thesis certified by the supervisor shall be submitted to the College/School/Institute, after submission of a research paper related to the Dissertation work in a UGC approved journal. A copy of the submitted research paper shall be attached to thesis.

7.19 The thesis shall be adjudicated by an external examiner selected by the University. For this, the

Principal of the College/School/Institute shall submit a panel of **three** examiners from among the list of experts in the relevant specialization as submitted by the supervisor concerned and Head of the Department.

7.20 If the report of the external examiner is unsatisfactory, the candidate shall revise and resubmit the Thesis. If the report of the examiner is unsatisfactory again, the thesis shall be summarily rejected. Subsequent actions for such dissertations may be considered, only on the specific recommendations of the external examiner and /or Dissertation Review Committee. No further correspondence in this matter will be entertained, if there is no specific recommendation for resubmission.

7.21 If the report of the examiner is satisfactory, the Head of the Department shall coordinate and make arrangements for the conduct of Dissertation Viva-Voce examination. The Dissertation Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who adjudicated the Thesis. The candidate has to secure a minimum of 50% of marks in Dissertation Evaluation (Viva-Voce) examination.

7.22 If he fails to fulfill the requirements as specified in 7.21, he will reappear for the Dissertation Viva-Voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree, unless he is asked to revise and resubmit his Dissertation Work by the board within a specified time period (within **four** years from the date of commencement of his first year first semester).

7.23 The Dissertation Viva-Voce External examination marks must be submitted to the University on the day of the examination.

7.24 For mandatory audit courses, a student has to secure 50 marks out of 100 marks (i.e. 50% of the marks allotted) in the continuous internal evaluation for passing the subject/course. These marks should also be uploaded along with the internal marks of other subjects.

7.25 No marks or letter grades shall be allotted for mandatory audit courses. Only Pass/Fail shall be indicated in Grade Card.

8.0 Re-Admission/Re-Registration

8.1 Re-Admission for Discontinued Student

A student, who has discontinued the M.Pharm. degree programme due to any reason whatsoever, may be considered for '**readmission'** into the same degree programme (with the same specialization) with the academic regulations of the batch into which he gets readmitted, with prior permission from the authorities concerned, subject to item 6.7.

8.2 If a student is detained in a subject (s) due to shortage of attendance in any semester, he may be permitted to **re-register** for the same subject(s) in the same category (core or elective group) or equivalent subject, if the same subject is not available, as suggested by the Board of Studies of that department, as and when offered in the subsequent semester(s), with the academic regulations of the batch into which he seeks re-registration, with prior permission from the authorities concerned, subject to item 3.2

8.3 ***A candidate shall be given only one-time chance to re-register and attend the classes for a maximum of two subjects in a semester***, if the internal marks secured by a candidate are less than 40% and failed in those subjects but fulfilled the attendance requirement. A candidate must re-register for failed subjects within four weeks of commencement of the class work and secure the required

minimum attendance. In the event of the student taking this chance, his Continuous Internal Evaluation (internal) marks and Semester End Examination marks obtained in the previous attempt stand cancelled.

9.0 Examinations and Assessment - The Grading System

9.1 Grades will be awarded to indicate the performance of each student in each Theory Subject, or Lab/Practicals, or Mini Project with Seminar, Dissertation, etc., based on the percentage of marks obtained in CIE + SEE (Continuous Internal Evaluation + Semester End Examination, both taken together) as specified in Item 7 above, and a corresponding Letter Grade shall be given.

9.2 As a measure of the student's performance, a 10-point Absolute Grading System using the following Letter Grades (PCI Guidelines) and corresponding percentage of marks shall be followed:

% of Marks Secured in a Subject/Course (Class Intervals)	Letter Grade (PCI Guidelines)	Grade Points
Greater than or equal to 90%	O (Outstanding)	10
80 and less than 90%	A (Excellent)	9
70 and less than 80%	B (Good)	8
60 and less than 70%	C (Fair)	7
50 and less than 60%	D (Average)	6
Below 50%	F (FAIL)	0
Absent	Ab	0

9.3 A student obtaining **'F'** Grade in any Subject is deemed to have 'failed' and is required to reappear as 'Supplementary Candidate' for the Semester End Examination (SEE), as and when conducted. In such cases, his Internal Marks (CIE Marks) in those subjects will remain as obtained earlier.

9.4 If a student has not appeared for the examinations, **'Ab'** Grade will be allocated to him for any subject and shall be considered 'failed' and will be required to reappear as 'Supplementary Candidate' for the Semester End Examination (SEE), as and when conducted.

9.5 A Letter Grade does not imply any specific marks percentage; it is only the range of percentage of marks.

9.6 In general, a student shall not be permitted to repeat any Subject/ Course (s) only for the sake of 'Grade Improvement' or 'SGPA/ CGPA Improvement'.

9.7 A student earns Grade Point (GP) in each Subject/ Course, on the basis of the Letter Grade obtained by him in that Subject/ Course. The corresponding 'Credit Points' (CP) are computed by multiplying the Grade Point with Credits for that particular Subject/ Course.

Credit Points (CP) = Grade Point (GP) x Credits …. For a Course

9.8 The student passes the Subject/ Course only when he **gets GP ≥ 6 (D Grade or above).**

9.9 The Semester Grade Point Average (SGPA) is calculated by dividing the Sum of Credit Points (ΣCP) secured from ALL Subjects/ Courses registered in a Semester, by the Total Number of Credits registered during that Semester. SGPA is rounded off to TWO Decimal Places. SGPA is thus computed as

$$\text{SGPA} = \left\{ \sum_{i=1}^{N} C_i G_i \right\} / \left\{ \sum_{i=1}^{N} C_i \right\}$$ **…. For each Semester,**

where 'i' is the Subject indicator index (taking into account all Subjects in a Semester), 'N' is the no. of Subjects 'REGISTERED' for the Semester (as specifically required and listed under the Course Structure of the parent Department), C_i is the no. of Credits allotted to the i^{th} Subject, and G_i represents the Grade Points (GP) corresponding to the Letter Grade awarded for that i^{th} Subject.

9.10 The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative performance of a student over all Semesters considered for registration. The CGPA is the ratio of the Total Credit Points secured by a student in ALL registered Courses in ALL Semesters, and the Total Number of Credits registered in ALL the Semesters. CGPA is rounded off to TWO Decimal Places. CGPA is thus computed from the I Year Second Semester onwards, at the end of each Semester, as per the formula

$$\textbf{CGPA} = \{ \sum_{j=1}^{M} C_j G_j \} / \{ \sum_{j=1}^{M} C_j \} \textbf{ ... for all S Semesters registered}$$

(ie., upto and inclusive of S Semesters, S ≥ 2),

where 'M' is the TOTAL no. of Subjects (as specifically required and listed under the Course Structure of the parent Department) the Student has 'REGISTERED' for from the 1st Semester onwards upto and inclusive of the Semester S (obviously M > N), 'j' is the Subject indicator index (taking into account all Subjects from 1 to S Semesters), C_j is the no. of Credits allotted to the j^{th} Subject, and G_j represents the Grade Points (GP) corresponding to the Letter Grade awarded for that j^{th} Subject. After registration and completion of I Year I Semester however, the SGPA of that Semester itself may be taken as the CGPA, as there are no cumulative effects.

Illustration of calculation of SGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
Course 1	4	A	9	4 x 9 = 36
Course 2	4	O	10	4 x 10 = 40
Course 3	4	C	7	4 x 7 = 28
Course 4	3	B	8	3 x 8 = 24
Course 5	3	A	10	3 x 10 = 30
Course 6	3	C	7	3 x 7 = 21
	Total Credits = 21			Total Credit Points = 179

SGPA = 179/21 = 8.52

Illustration of calculation of CGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
I Year I Semester				
Course 1	4	A	9	4 x 9 = 36
Course 2	4	A	9	4 x 9 = 36
Course 3	4	B	8	4 x 8 = 32
Course 4	3	O	10	3 x 10 = 30
Course 5	3	B	8	3 x 8 = 24

Course 6	3	D	6	3 x 6 = 18
I Year II Semester				
Course 7	4	B	8	4 x 8 = 32
Course 8	4	O	10	4 x 10 = 40
Course 9	4	A	9	4 x 9 = 36
Course 10	3	D	6	3 x 6 = 18
Course 11	3	C	7	3 x 7 = 21
Course 12	3	A	9	3 x 9 = 27
	Total Credits = 42			Total Credit Points = 350

CGPA = 350/42 = 8.33

10.0 Award of Degree and Class

10.1 If a student who registers for all the specified Subjects/ Courses as listed in the Course Structure, satisfies all the Course Requirements, and passes the examinations prescribed in the entire PG Programme (PGP), and secures the required number of **98** Credits (with CGPA ≥ 6.0), shall be declared to have 'QUALIFIED' for the award of the M.Pharm. Degree in the chosen specialization of Pharmacy that he was admitted into.

10.2 Award of Class

After a student has earned the requirements prescribed for the completion of the programme and is eligible for the award of M.Pharm. Degree, he shall be placed in one of the following three classes based on the CGPA:

Class Awarded	CGPA
First Class with Distinction	≥ 7.50
First Class	6.00 ≤ CGPA < 7.49
Second Class	5.00 ≤ CGPA < 5.99

A student with final CGPA (at the end of the **PGP) < 6.00** shall not be eligible for the Award of Degree.

11.0 Withholding of Results

If the student has not paid the dues, if any, to the University or if any case of indiscipline is pending against him, the result and degree of the student will be withheld and he will not be allowed into the next semester.

12.0 General

12.1 **Credit**: A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.

12.2 **Credit Point:** It is the product of grade point and number of credits for a course.

12.3 Wherever the words "he", "him", "his", occur in the regulations, they shall include "she", "her".

12.4 The academic regulation should be read as a whole for the purpose of any interpretation.

12.5 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the University is final.

12.6 The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

S.No	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1.(a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject to the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination).	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. Incase of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject to the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the	Expulsion from the examination hall and cancellation of performance in that subject and

	question paper during the examination or answer book or additional sheet, during or after the examination.	all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent/ any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in- charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	Incase of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any par there of inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already

		appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
   - (i) A show cause notice shall be issued to the college.
   - (ii) Impose a suitable fine on the college.
   - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.PHARMACY (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)
R22 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2022-23 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutics-I	3	1	0	4
Professional Core-II	Applied Biopharmaceutics and Pharmacokinetics	3	1	0	4
Professional Elective-I	1. Advanced Physical Pharmaceutics 2. Drug Regulatory affairs 3. Total Quality Management	3	1	0	4
Professional Elective-II	1. Cosmetics and Cosmeceuticals 2. Pharmaceutical Validation 3. Stability of Drugs and Dosage Forms	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutics – I Lab	0	0	6	3
Laboratory- II	Applied Biopharmaceutics and Pharmacokinetics Lab	0	0	6	3
Audit - I	Audit Course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	**16**	**4**	**16**	**26**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Modern Pharmaceutics - II	3	1	0	4
Professional Core-IV	Advanced Drug Delivery Systems	3	1	0	4
Professional Elective-III	1. Industrial Pharmacy 2. Herbal Cosmetics 3. Pharmaceutical Management	3	1	0	4
Professional Elective-IV	1. Nano based Drug Delivery Systems 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Modern Pharmaceutics – II Lab	0	0	6	3
Laboratory- IV	Advanced Drug Delivery System Lab	0	0	6	3
	Mini Project	2	0	0	2
Audit - II	Audit Course- II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	**16**	**4**	**16**	**26**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production area, Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva voce	0	0	8	4
	Dissertation Work Review – II	0	0	24	12
	TOTAL	**6**	**2**	**32**	**24**

II YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	TOTAL	**0**	**0**	**44**	**22**

***For Dissertation Work Review - I, Please refer R22 Academic Regulations.**

Audit Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS –I (Professional Core-I)

Course Objectives: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcome: Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

UNIT I
Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies as per ICH**.**

UNIT II
Formulation development of solid dosage forms – I: New materials, excipient science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipient, co-processed materials, methods of preparation and evaluation.

UNIT III
Formulation development of solid dosage forms– II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.
Microencapsulation- types, methodology, problems encountered.

UNIT IV
Formulation development of soft and hard gelatin capsules: Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V
Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

6. Pharmaceutical statistics by Bolton

REFERENCE BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and IsadoreKanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Core – II)

Course Objectives: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Course Outcomes: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

UNIT I

a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

a. Distribution: Apparent volume of distribution and its determination, factors affecting.
b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
c. Elimination: Over all apparent elimination rate constant, and half life.
   All the above under the following conditions:
   1. Intravenous infusion
   2. Multiple dose injections
d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants **–** Zero order, first order,Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

- ❖ Numerical problems associated with all units, if any.

TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz, Pharmamed Press

REFERENCE BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS (Professional Elective – I)

Course Objectives: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

Course Outcomes: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

UNIT I
Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II
Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III
Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV
Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.
Characterization of API and excipients: Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications and interpretations
X Ray Diffraction methods: Origin of x-rays, principle, advantages, disadvantages, instrumentation, applications and interpretations.

UNIT V
Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid-state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

TEXT BOOKS:
1. Physical Pharmacy, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol. 4.
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II.

4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013.

REFERENCE BOOKS:

1. Dispersive systems I, II, and III.
2. Robinson. Controlled Drug Delivery Systems.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

DRUG REGULATORY AFFAIRS (Professional Elective-I)

Course Objectives: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcomes:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC& BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Managemant, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product DirectorateDMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.

3) MHRA – Medicines and Health Care Products Regulatory Agency

d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Text Book of Forensic Pharmacy by C K Kokate, Pharmamed Press
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

TOTAL QUALITY MANAGEMENT (Professional Elective - I)

Course Objectives: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

Course Outcomes: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

UNIT - I
Concepts and Philosophy of TQM, GLP, GMP (orange guide).

UNIT – II
Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

UNIT - III
Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP). Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms. Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc., Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document.

UNIT - IV
Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratoginicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

UNIT - V
Globalization of drug industry, present status and scope of pharmaceutical industry in India. WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

TEXT AND REFERENCE BOOKS:

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.

2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance, USP.
9. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
11. Total Quality Management, An integrated Approach by D. R. Kiran, BS Publications
12. Total Quality Management, 3rd edition by Joel E. Ross. CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

COSMETICS AND COSMECEUTICALS (Professional Elective - II)

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCE BOOKS:

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3 rd edition
5. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetics for the Skin: Physiological and Pharmaceutical Approach by A. K. Mohiuddin, Pharmamed Press.
7. Cosmetic and Toiletries recent suppliers' catalogue.
8. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL VALIDATION (Professional Elective - II)

Course Objective: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcome: Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

- Validate the manufacturing facilities

REFERENCE BOOKS:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton &Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Upǁ, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Pharmaceutical Facilities: Design, Layouts and Validation, 2nd Ed, Potdar, Pharmamed Press.
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)

Course Objectives: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT - I
Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT - II
Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.
Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT - III
Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.
Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

UNIT - IV
General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT - V
Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.
Stability studies: Concept of stability studies.
a) cGMP& ICH guidelines for Accelerated stability Testing.
b) Interaction of containers & closure Compatibility Testing.

REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.,BSP Books

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I:

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II:

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III:

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV:

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT-V:

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, “Research methodology: an introduction for science & engineering students’”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

REFERENCE BOOKS:

1. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
2. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
3. Mayall, “Industrial Design”, McGraw Hill, 1992.
4. Niebel, “Product Design”, McGraw Hill, 1974.
5. Asimov, “Introduction to Design”, Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New Technological Age”, 2016.
7. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS – I LAB (Laboratory - I)

List of Experiments:

1. To carry out the preformulation studies of solid dosage forms**.**
2. To study the effect of compressional force on tablet disintegration time
3. To study the micromeritic properties of powders and granules
4. To study the effect of particle size on dissolution of capsules.
5. To study the effect of binders on dissolution of tablets
6. To study enteric coated tablets dissolution in relevant pH.
7. Accelerated stability testing of different tablets
8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
10. Preparation of paracetamol tablets and comparison with marketed products
11. Design of experiments (DOE) in the optimization of an immediate release tablets.
12. Calculation of shelf life using accelerated stability data,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB (Laboratory- II)

List of Experiments:

1. Analysis of dissolution by various data-kinetic modelling.
2. Calibration curve of different API's by UV/HPLC/HPTLC
3. Dissolution of immediate release, sustained release and delayed release.
4. Evaluation of drug-protein binding analysis
5. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
6. Calculation of K_a(absorption rate constant) absorption curve- Wagner nelson method , Loo-Riegel method.
7. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
8. Construction of IVIVC from the data
9. Calculation of Urinary Pharmacokinetics
10. Calculation of Bioavailability and Bioequivalence Studies
11. Permeation studies of Franz diffusion cell
12. Drug Release from semisolids by Agargel method or Franz diffusion cell.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS - II (Professional Core - III)

Course Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students also understand about the cosmetics and nutraceuticals.

Course Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and nutraceuticals.

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. Pilot plant: Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.

b. Scale up: Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilization methods (Moist heat, dry heat, filtration, radiation, gaseous sterilization), product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

a. Cosmetics: Formulation approaches, preparation & method of manufacturing labelling & Q.C. of anti-ageing products, sun screen lotion and fairness creams.

b. Nutraceuticals:

1. Introduction, source, manufacture and analysis of glucosamine & cartinine.
2. Monographs: General and specific properties of glucosamine & cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

b. Air handling systems: Study of AHUs, humidity & temperature control.

TEXT BOOKS:

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.

4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr.
5. Nicholas G. Popovich, Howard C. Ansel.
6. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
7. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

REFERENCE BOOKS:

1. Bentley`s Text Book of Pharmaceutics by EA Rawlins.
2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Nutraceuticals, 2nd edition by Brian lock wood.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS (Professional Core - IV)

Course Objectives: The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

Course Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

UNIT I
Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems
a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT II
Design, fabrication, evaluation and applications of the following
a. Implantable Therapeutic systems
b. Transdermal delivery systems
c. Ocular and Intrauterine delivery systems
d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles for vaccine development

UNIT III
Biochemical and molecular biology approaches for drug delivery using following technologies
a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT IV
Biochemical and molecular biology approaches to control drug delivery of
a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT - V
Drug targeting to particular organs
a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

TEXT BOOKS:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.

5. Advances in Drug Delivery, 4 Vol. set, Rao Madhusudan Y, Pharmamed Press
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
7. Oral Drug Delivery Technology, 2nded, by Aukunuru Jithan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

INDUSTRIAL PHARMACY (Professional Elective - III)

Course Objectives: The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms

Course Outcome: The students will explain the machinery involved in milling, mixing, filtration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient feature1s of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

UNIT I
Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, granulation, drying and blending.

UNIT II
a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.
b. Qualification of equipment (IQ, OQ, PQ)

UNIT III
Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT IV
Effluent Testing and Treatment: Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and sound pollution.

UNIT V
Validation: Regulatory basis, validation process for solid dosage forms, sterile products, and liquid dosage forms.

TEXT BOOKS:
1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.
6. Industrial Pharmacy: A Comprehensive Approach, D K Tripathi, Pharmamed Press.

REFERENCE BOOKS:

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Bentley's Text book of Pharmaceutics by EA Rawlins.
4. CGMP, H.P.P. Sharma

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

HERBAL COSMETICS (Professional Elective - III)

Course Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

UNIT - I

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.
Regulatory Provisions relation to manufacture of cosmetics: -
License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

UNIT - II

a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
c) General principles of quality control of herbal cosmetics

UNIT - III

Skin care Products: Physiology and chemistry of skin,Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT - IV

Hair care Products: Hair structure and its chemistry
Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT - V

Herbs in cosmetics:

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

REFERENCE BOOKS:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL MANAGEMENT (Professional Elective - III)

Course Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

Course Outcomes:

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing, and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labsetc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.

4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper &Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management 3rd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
11. Personnel Management and Industrial Relations by P. C.Tripathi.
12. Pharmaceutical Industrial Management by G. Vidya Sagar, Pharmamed Press.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective - IV)

Course Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT - I – Introduction to Nanotechnology

a. Definition of nanotechnology
b. History of nanotechnology
c. Unique properties and classification of nanomaterials
d. Role of size and size distribution of nanoparticles properties.
e. Marketed formulations based on nanotechnology and science behind them

UNIT - II – Synthesis of Nanomaterials

Physical, chemical and biological Methods
Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferasomes, micelles, aquasomes and nanoemulsions

UNIT - III - Biomedical applications of Nanotechnology

a. Nanotechnology products used for in vitro diagnostics
b. Improvements to medical or molecular imaging using nanotechnology
c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT - IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

TEXT AND REFERENCE BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)

5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano-Carrier Systems Theories, Methods & Applications, Amit K. Goyal, Goutam Rath,Pharmamed Press.
7. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
8. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
9. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley &Sons,2009
10. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
11. Introduction to Nano Science and Technologies, AnkaneyuluYerramilli, BS Publications. 2016

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

Course Outcomes: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin

Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCE BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T. Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)

Course Objectives: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: Upon completion of the course, the student shall be able to;

- explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT I

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT II

Clinical Trials: Types and Design:

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III

Clinical Trial Documentation:

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety
data.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary,Pharmamed Press.
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS – II LAB (Laboratory- III)

List of Experiments:

1. Scale up calculations from R&D to pilot plant for the following unit operations
   a) Wet granulations using RMG/PLM
   b) Blending & Lubrications
   c) Film coating
2. Preparation of Injectables, Ampoules & Vials
3. Preparation of Ophthalmic products, Eye drops and Eye ointments
4. Preparation of Dry powder Inhalations
5. Formulation Development and Demonstration of function of DPI of marketed products
6. Formulation of Aerosol Demonstration of marketed products

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS LAB (Laboratory- IV)

List of Experiments:

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and Evaluation of sustained release Oral Matrix Tablet (2 experiments)
3. Formulation and Evaluation of sustained release Oral Reservoir System (2 experiments)
4. Formulation and Evaluation of Microspheres / Microencapsules (2 experiments)
5. Study of in-vitro Dissolution of various SR products in market (2 experiments)
6. Formulation and Evaluation of Transdermal Films (2 experiments)
7. Formulation and Evaluation of Mucoadhesive System (2 experiments)
8. Preparation and Evaluation of Enteric Coated Pellets / Tablets (2 experiments)
9. Preparation and Evaluation of Liposomes, Niosomes and Nanoparticles

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

BIOSTATISTICS (Professional Elective - V)

Course Objectives: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcomes: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression
Probability rules: Binomial, Poison and Normal distribution.

UNIT IV

Experimental designing, planning of an experiment, replication and randomization.
Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V

Hypothesis testing: Student 't' test, Chi square test,
Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
6. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, KPR Chowdary, Pharmamed Press.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.
Course Outcomes: On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards

UNIT I
Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.
Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II
Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT III
Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT IV
Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V
Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCE BOOKS:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.\
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT
(Professional Elective - V)

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcomes: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

UNIT I
Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II
Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III
Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV
Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V
Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCE BOOKS:
1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New
6. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

UNIT-I:
Introduction:
Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.
Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:
Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:
Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:
Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:
Disaster Mitigation:
Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. R. Nishith, Singh AK, “Disaster Management in India: Perspectives, issues and strategies “’New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.),” Disaster Mitigation Experiences and Reflections”, Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies”, Deep &Deep Publication Pvt. Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. “Abhyaspustakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. “India’s Glorious Scientific Tradition” Suresh Soni, Ocean books (P) Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT-I:
Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:
Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:
Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:
Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:
History of Making of the Indian Constitution: History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble**,** Salient Features.

UNIT-II:
Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:
Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:
Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:
Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don't's in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

UNIT-V:
i) Various yog poses and their benefits for mind & body
ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P. Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.PHARMACY (PHARMACEUTICAL ANALYSIS)
R22 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2022-23 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	1	0	4
Professional Core-II	Pharmaceutical Food Analysis	3	1	0	4
Professional Elective-I	1. Advanced Pharmaceutical Analysis 2. Drug Regulatory Affairs 3. Phytochemistry	3	1	0	4
Professional Elective-II	1. Pharmaceutical Validation 2. Cosmetics and Cosmeceuticals 3. Stability of Drugs and Dosage forms	3	1	0	4
	Research Methodology & IPR	2	0	0	2
Laboratory-I	Modern Pharmaceutical Analytical Techniques lab	0	0	6	3
Laboratory-II	Pharmaceutical food Analysis Lab	0	0	6	3
Audit - II	Audit course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	**16**	**4**	**16**	**26**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Advanced Instrumental Analysis - I	3	1	0	4
Professional Core-IV	Pharmaceutical Quality Control & Quality Assurance	3	1	0	4
Professional Elective-III	1. Modern Bio-analytical Techniques 2. Herbal Cosmetics 3. Pharmacoepidemiology & Pharmacoeconomics	3	1	0	4
Professional Elective-IV	1. Advanced Instrumental Analysis - II 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Advanced Instrumental Analysis I Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Quality Control & Quality Assurance Lab	0	0	6	3
	Mini project	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production Area Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
Dissertation	Comprehensive Viva Voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	Total	**6**	**2**	**32**	**24**

II YEAR II SEMESTER

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	Total	**0**	**0**	**44**	**22**

***For Dissertation Work Review - I, Please refer R22 Academic Regulations.**

Audit Courses I&II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Professional Core - I)

Course Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. **Column Chromatography:** Adsorption and partition, theory, preparation, procedure and methods of detection
b. **Thin Layer Chromatography:** Theory, preparation, procedures, detection of compounds
c. **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II

a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
b. **HPLC:** Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. **UV-Visible spectroscopy:** Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. **IR spectroscopy:** Basic principles -Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, ***interpretation of spectra*** and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect (NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
6. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7. Organic Chemistry by I. L. Finar
8. Organic spectroscopy by William Kemp
9. Quantitative Analysis of Drugs by D. C. Garrett
10. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11. Spectrophotometric identification of Organic Compounds by Silverstein
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL FOOD ANALYSIS (Professional Core – II)

Course Objective: This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Course Outcome: At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

UNIT I

a. **Carbohydrates:** Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates
b. **Proteins**: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

UNIT II

Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT III

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

UNIT IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT V

a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.

TEXT BOOKS:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Food Chemistry and Nutrition: A Comprehensive Treatise, Sumathi S, Pharmamed Press.
3. David Pearson, The Chemical Analysis of Foods, 7th edn, Churchill Livingstone, Edinburgh.
4. Nielsen S. Introduction to chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
5. Indian Pharmacopoeia 2012

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - I)

Course Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

Course Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods
E. Neutralization
F. Acid – Base

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl
E. Amino Acids

UNIT III

a. Reference Standards: Types, preparation methods and uses.

b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP
   a. MBTH (3-methyl-2-benzothiazolone hydrazone)
   b. F.C. Reagent (Folin-Ciocalteu)
   c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
   d. 2, 3, 5 - *tri*Phenyltetrazolium salt
   e. 2,6 *di* -ChloroquinoneChlorimide
   f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
   g. Carr – Price Reagent
   h. 2,4 - DNP

UNIT IV

a. Analysis of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.

b. Excipients of interest: Disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT V

a. **Dissolution Tests:** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.

b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

TEXT BOOKS:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Fundamentals of Analytical Chemistry, DK Sarkar, Pharmamed Press

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
DRUG REGULATORY AFFAIRS (Professional Elective - I)

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    3) MHRA – Medicines and Health Care Products Regulatory Agency

d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHYTOCHEMISTRY (Professional Elective - I)

Course Objective: Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phytoconstituents of different categories.

Course Outcome: On the basis of chemistry data of phytoconstituents students will acquire knowledge on various types of phytoconstituents present in the plants.

UNIT I

Biosynthetic pathways and Radio tracing techniques: containing drugs:

a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.
b) Study of Biosynthetic pathways of of following phyto-pharmaceuticals: Atropine, Morphine, Cardiac glycosides and Flavonoids.

UNIT II

Drug discovery and development: Approaches to discovery and development of natural products as potential new drugs. Sourcing and archiving Natural products for discovery, evaluating natural products for therapeutic properties, Identifying the biologically active Natural products, the lead structure selection process and Optimization with suitable examples from the following source: artemesin, andrographolides.

UNIT III

a) Extraction/Isolation methods for specific Phytochemical groups, Choice of solvents and Interfering compounds for general Isolation and purification of desired phytoconstituents.
b) Recent sophisticated extraction techniques like: Super critical fluid extraction and Ultra-sonic extraction. Separation of phytoconstituents by Vacuum and Flash column chromatography.

UNIT IV

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses of the following phyto-pharmaceuticals:

a) Atropine, caffeine, Morphine and brief account on its derivatives and analogues
b) Camptothecin, Digoxin
c) Taxol, Podophyllotoxin

UNIT V

a. Natural colorants: Biological Source, colouring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric
b. Flavours and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

REFERENCES:

1. Phytochemical methods of chemical analysis by Harbone
2. Modern methods of plant analysis- peach & M. V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8. Plant drug analysis by Wagner
9. Clarke's isolation & identification of drugs by AC Mottal

10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Pharmacognosy and Phytochemistry: A Comprehensive Approach, S L Deore, Pharmamed Press
14. Medicinal chemistry and drug discovery by Burger's
15. Foye's Principles of medicinal chemistry.
16. Pharmacognosy and phytochemistry by Biren seth
17. Herbal Perfumes and cosmetics by Panda
18. Herbal Drug Technology by SS Agarwal
19. Pharmacognosy and Phytochemistry by VD Rangari.
20. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL VALIDATION (Professional Elective - III)

Course Objective: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcome: Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

- Validate the manufacturing facilities

REFERENCES:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar,Pharmamed Press

6. Michael Levin, Pharmaceutical Process Scale-Upǁ, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
COSMETICS AND COSMECEUTICALS (Professional Elective - II)

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry’s Cosmeticology. 8th edition.

2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetic and Toiletries recent suppliers' catalogue.
7. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective –II)

Course Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

UNIT IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

REFERENCES:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"

2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”.
3. Pharmaceutical Research Methodology and Biostatistics, B Subba Rao, Pharmamed Press.
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press.

REFERENCES:

1. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
2. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
3. Mayall, “Industrial Design”, McGraw Hill, 1992.
4. Niebel, “Product Design”, McGraw Hill, 1974.
5. Asimov, “Introduction to Design”, Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New
7. Technological Age”, 2016.
8. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)

LIST OF EXPERIMENTS:

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL FOOD ANALYSISLAB (Laboratory –II)

LIST OF EXPERIMENTS:

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors & food additives in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
9. Assay of any two Antihistamines (API & dosage forms) official in IP
10. Assay of any two Diuretics (API & dosage forms) official in IP
11. Microbiological assay of any two Antibiotics official in IP

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS – I (Professional Core - III)

Course Objectives: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

UNIT I

X-Ray diffraction methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT II

a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
b. **Super critical fluid chromatography**: Principles, instrumentation, pharmaceutical applications.

UNIT III

Capillary Electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE,

UNIT IV

a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
b. **DTA**: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

UNIT V

Scanning electron microscope (**SEM**): Principles, Instrumentation and applications.
Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Professional Core – IV)

Course Objectives: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

UNIT I

a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
b. **Impurities in new drug products**: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT II

a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

UNIT III

a. Organization and personnel, responsibilities, training hygiene
b. **Premises**: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT IV

a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms

a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra

4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

REFERENCES:

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. Pharmaceutical Quality Assurance and Management, K. P. Bhusari, Pharmamed Press
5. SOP Guidelines by D.H. Shah
6. Quality Assurance Guide by OPPI
7. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
8. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
MODERN BIO-ANALYTICAL TECHNIQUES (Professional Core - IV)

Course Objectives: This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Course Outcomes: Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies

UNIT I

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

UNIT II

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III

Bioanalysis and bioanalytical method validation:

a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV

Pre-Formulation: A consideration of following characteristics of medicinal agents in their dosage form:

Physical characteristics-Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

Chemical Characteristics-Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug – Excipient compatibility studies.

UNIT V

a. Automation and computer-aided analysis, LIMS: The concept of auto samplers and high throughput analysis, computer-controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).

b. Drug Product Performance, In Vivo: Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies.

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.

4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines
11. Palmer

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
HERBAL COSMETICS (Professional Elective - III)

Course Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed tovarious preparations of herbal cosmetics.

UNIT I
Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.
Regulatory Provisions relation to manufacture of cosmetics: -
License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

UNIT II
a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding, Packing.
c) General principles of quality control of herbal cosmetics

UNIT III
Skin care Products: Physiology and chemistry of skin, Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV
Hair care Products: Hair structure and its chemistry
Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT V
Herbs in cosmetics:
A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

REFERENCES:
1. Cosmetics- Formulation, Manufacturing and Quality control –P. P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm. I Year II Sem (Pharmaceutical Analysis)
PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Professional Elective - III)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)
ADVANCED INSTRUMENTAL ANALYSIS – II (Professional Elective - IV)

Course Objectives: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various electrochemical methods, flourimetry, AAS, RIA, ELISA etc. which help them in further projects works and also industrial opportunities

UNIT I

Polarography – Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.
Amperometry - Principles, instrumentation and applications including amperometric titrations.

UNIT II

a. **Potentiometry –** Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
b. **Conductometry–** Introduction, Conductivity cell, Conductometric titrations, applications

UNIT III

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT IV

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT V

a. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.
b. **ELISA:** Principle, types and application of ELISA

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b. Sulfides: Diallylsulfides, Allyltrisulfide.
c. Polyphenolics: Reservetrol
d. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e. Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f. Phytoestrogens, Isoflavones, daidzein, Geebustin, lignans
g. Tocopherols

UNIT III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin
c. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCES:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)

Course Objective: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT I

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT II

Clinical Trials: Types and Design: Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and Nationalprogrammesrelatedtopharmacovigilance.RolesandresponsibilitiesinPharmacovigilance.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance.

Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, ArisG Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS-I LAB (Laboratory –III)

LIST OF EXPERIMENTS:

1. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
2. Determination of compounds of sodium, potassium and calcium by Flame photometry.
3. Estimation of riboflavin/quinine sulphate by flourimetry
4. Assay of official compounds by potentiometric titrations **(Any 2)**
5. Assay of official compounds by conductimetric titrations **(Any 2)**
6. Demonstration on ELISA
7. Quenching of fluorescence
8. Perform phosphate interference on absorption of calcium

(Note: Minimum of two experiments covering each of the above-mentioned topics)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB

LIST OF EXPERIMENTS:

1. QC tests for tablets (minimum 2 experiments)
2. QC tests for capsules (minimum 2 experiments)
3. QC tests for oral liquids monophasic (minimum 2 experiments)
4. QC tests for oral liquids biphasic (minimum 2 experiments)
5. Forced degradation studies of some drugs.
6. Interpretation of spectras by IR, NMR and MASS
7. Assay of drug formulations using UV-Spectrophotometer (Any four)
8. Demonstration of functional groups of the given samples by IR Spectrophotometer.
9. Physicochemical tests for water
10. Solubility studies of weakly acidic and weakly basic drugs.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)
BIOSTATISTICS (Professional Elective - V)

Course Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

UNIT I
Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II
Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III
Measures of Correlation and Regression
Probability rules: Binomial, Poison and Normal distribution.

UNIT IV
Experimental designing, planning of an experiment, replication and randomization.
Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V
Hypothesis testing: Student 't' test, Chi square test,
Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCES:
1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)
SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcome: On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

UNIT I

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT III

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT IV

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)
PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT (Professional Elective - V)

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcome: At the end of the semester student will get an idea about Industrial area design and packaging of different formulations and its stability conditions.

UNIT I
Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II
Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III
Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV
Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V
Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCES:

1. Lachman; Lieberman Herbert A.; Kanig, The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester
6. Pharmaceutical Facilities: Design, Layouts and Validation,Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

UNIT-I:
Introduction:
Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.
Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:
Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:
Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:
Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:
Disaster Mitigation:
Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. R. Nishith, Singh AK, “Disaster Management in India: Perspectives, issues and strategies “’New Royal book Company.
2. Sahni, Pardeep Et. Al. (Eds.),” Disaster Mitigation Experiences and Reflections”, Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies”, Deep &Deep Publication Pvt. Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. “Abhyaspustakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha - Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. “India’s Glorious Scientific Tradition” Suresh Soni, Ocean books (P) Ltd., New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT-I:
Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:
Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:
Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:
Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:
History of Making of the Indian Constitution: History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble**,** Salient Features.

UNIT-II:
Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:
Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:
Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayat raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:
Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners.State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:
Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:
Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:
Evidence on the effectiveness of pedagogical practices, Methodology for the in depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:
Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:
Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don't's in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

UNIT-V:
i) Various yog poses and their benefits for mind & body
ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2. "Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Analysis)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. "Srimad Bhagavad Gita" by Swami SwarupanandaAdvaita Ashram (Publication Department), Kolkata.
2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.

R22 M. PHARMACY LIST OF OPEN ELECTIVES

Pharmacy Practice	Pharmaceutical Regulatory Affairs	Industrial Pharmacy	Pharmaceutical Chemistry	Pharmaceutics/ Pharmaceutical Technology
1. Cosmeticology 2. Pharmaceutical Administration 3. Hazards and Safety management 4. Project Management 5. Audits and regulatory compliance	1. Screening Methods in Pharmacology 2. Entrepreneurship Management 3. Cosmetic science 4. Hazards and Safety management 5. Audits and regulatory compliance	1. Screening Methods in Pharmacology 2. Entrepreneurship Management 3. Cosmetic science 4. Hazards and Safety management 5. Audits and regulatory compliance	1. Entrepreneurship Management 2. Hazards and Safety management 3. Audits and regulatory compliance 4. Pharmaceutical validation 5. Nutraceuticals	1. Screening Methods in Pharmacology 2. Entrepreneurship Management 3. Cosmetic science 4. Hazards and Safety management 5. Audits and regulatory compliance
Pharmaceutical Quality Assurance	**Pharmacology**	**Pharmaceutical Analysis**	**Pharmacognosy**	
1. Entrepreneurship Management 2. Cosmetic Science 3. Nutraceuticals 4. Nano Based Drug Delivery Systems 5. Pharmacoepidemiology and Pharmacoeconomics	1. Cosmeticology 2. Pharmaceutical Administration 3. Drug Regulatory affairs 4. Project Management 5. Audits and regulatory compliance	1. Screening Methods in Pharmacology 2. Entrepreneurship Management 3. Cosmetic Science 4. Hazards and Safety Management 5. Audits and Regulatory Compliance	1. Screening Methods in Pharmacology 2. Cosmetic Science 3. Nutraceuticals 4. Entrepreneurship Management	

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacy Practice)

COSMETICOLOGY (Open Elective)

Course Objective: This subject will impart knowledge about physiological structure of skin, hair, nail and eye. This gives the information about rheological properties of different cosmetic properties. It will teach the students on preparation and evaluation of different cosmetic products and their excipients. It will teach the students in developing cosmetic safety and new technology in developing cosmetics.

Course Outcome: Upon completion of the course, the student shall be able to,

- Explain the physiological structures of skin, hair, nail and eye.
- It gives the knowledge about rheological property determination
- Explain the evaluation process, safety use of cosmetics and new technology development.
- Explain the principles involved in liposomes, multiple emulsions and creams.

UNIT I

1) Physiological consideration: skin, hair, nail and eye - in relation to cosmetic application.
2) Rheology of cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

UNIT II

3) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics.
4) Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

UNIT III

5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
6) Herbal cosmetics: Formulation development

UNIT IV

7) Packaging: Package development and design for cosmetics including aerosol packs
8) Regulatory requirements: Manufacturing and sale of cosmetics

UNIT V

9) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
10) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

RECOMMENDED BOOKS:

1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
2. J.B. Wilkinson and R.J. Moore; Harry's cosmetology; Longman Science and Technical.
3. S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4. E.G. Thomssen; Modern cosmetics; Universal Publishing Corporation.
5. M.S. Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
6. R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
7. H.R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8. W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.

9. C.G. Gebelein, T.C.Cheng and V.C. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10. L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11. W.A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3, Chapman and Hall
12. Dr.Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacy Practice)

PHARMACEUTICAL ADMINISTRATION (Open Elective)

Course Objective: This subject will provide principles of pharmaceutical industrial management, forms of business organization, plant location and layout. It will teach the students on workman safety, export and import of drugs and pharmaceuticals and briefly on industrial accounting.

Course Outcome: Upon completion of the course, the student shall be able to, Explain the Indian pharmaceutical industry development, knowledge about Pharmaxil and its involvement Explain the books of accounting, journals, ledger, cashbook and balance sheet.

UNIT I
Pharmaceutical Industrial administration: Principles of Pharmaceutical Industrial Management in relation to the Introduction to forms of Business Organization. Manufacturing Management: Plant location, factory building lay-out, production management goals and organization, operating problems, production policy, initiation of production, purchasing and inventory control, works lay-out and plant management.

UNIT II
Workman Safety: measures to health hazards and prevention of environmental pollution. Organization of Distribution and Marketing: Factors in distributions, Sales organization and sales promotions. General principles of medical detailing. Export and Import trade. GATT, WTO - New product development.

UNIT III
Indian pharmaceutical industry: Pharmaceutical industry in India, milestones in the development of pharmaceutical industry, current status and its role in national economy and national health. Structure of the industry, organized sector, small sector, manufacture of pharmaceuticals in public sector. Progress in the manufacture of basic drugs – synthetic and drugs of vegetable origin.

UNIT IV
Export and import of drugs and pharmaceuticals –knowledge of PHARMEXIL. Various types of insurances including marine insurance. Pharmaceutical associations and societies, statutory councils governing the profession. Principle of Drug store and community pharmacy administration: Drug store management: Drug store planning and lay – out, sales promotion and salesmanship in drug store. Accounting records in drug stores.

UNIT V
Elements of industrial accountancy: Elements of double entry, books of accounts, journal, ledger and cashbook. The balance sheet, profit and loss account. Principles of costing and estimating.

RECOMMENDED BOOKS:

1. Essentials of management by Dr. Herold Koontz and Heinz Weitnrich, published by McGraw Hill publishing company.
2. Managing productivity in organizations by Kopelman, published by McGraw Hill publishing company.
3. Pharmacy Administration by G. Vidya Sagar
4. Effective supervision: A practical approach by Hodgetts, published by McGraw Hill publishing company.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacy Practice)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India,
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacy Practice)

PROJECT MANAGEMENT (Open Elective)

Course Objective: This subject will provide introduction of project life cycle, its duties, planning for project life cycle leaders and their involvement project management. It will teach the students on role of project managers, clients, customers etc. This subject also focuses on project planning process, executing and heading the project team and responsibilities.

Course Outcome: Upon completion of the course, the student shall be able to, Explain the project management and its life cycle involves in different duties as project manager, clients and customers Explain the responsibilities of key players involved in project management Execute project as project leaders and team responsibilities.

UNIT I
Introduction & Project Life Cycle:
The difference between a project manager and a project engineer / project leader, duties of a project engineer /project leader, relationship between scope/schedule/budget/resources and how it relates to all project activities
Project Life Cycle and how it relates to project definition and control, feasibilities and feasibility study, key elements of working in a group and group dynamics.

UNIT II
Pre-Planning for Project Management:
Importance of project management, organizing for project management, Role of project manager, Role of clients, customers and others, setting up planning and control system.

UNIT III
Project Planning Process:
Defining project, creating work breakdown structure, estimating activities, sequencing activities, calculating the critical path, scheduling project, resources planning, preparing planning budgets, approval of projects, setting up a monitoring and control process.

UNIT IV
Executing the Project:
Initiating the project, controlling project objectives, reporting on project objectives, controlling changes in the project, conducting project evaluations, managing risks in project management,
Closing the project.

UNIT V
Heading the Project Team:
Developing project teams, managing conflicts, communicating effectively, holding effective meetings, making team decisions, using sources of power wisely, making changes, managing performance

RECOMMENDED BOOKS:

1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
2. Project management: The managerial process By Clifford F. Gray and Eric W. Larson Publisher: Tata Mc Graw Hill Third edition
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
4. Project management By Jeffery K. Pinto Publisher: Prentice-Hall Year of publication 2007.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacy Practice)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

SCREENING METHODS IN PHARMACOLOGY (Open Elective)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Guidelines and Screening Methods of Pharmacology, Surendra H. Bodakhe, Pharmamed Press

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

COSMETIC SCIENCE (Open Elective)

Course Objectives: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcomes: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I
Classification of cosmetics and cosmeceutical products.
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.
Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.
Skin: Basic structure and function of skin.
Hair: Basic structure of hair, hair growth cycle.
Oral Cavity: Common problem associated with teeth and gems.

UNIT II
Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.
Anti perspants and Deodrants: Actives and MOA.
Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.
Chemistry and formulation of Para-phylene di amine-based hair dye.
Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III
Sun protection, classification of sunscreens and SPF.
Role of herbs in cosmetics:
Skin care – Aloe and turmeric
Hair care – Henna and amla
Oral care – Clove and neem
Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV
Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V
Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.
Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.
Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.
Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:
1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.

2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. BharuchaErach, The Biodiversity of India, Mapin Pu blishingPvt. Ltd., Ahmedabad – 380013, India.
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to;

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Industrial Pharmacy)

SCREENING METHODS IN PHARMACOLOGY (Open Elective)

Course Objective:
The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome:
The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:
1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Industrial Pharmacy)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Industrial Pharmacy)

COSMETIC SCIENCE (Open Elective)

Course Objectives: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcomes: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I

Classification of cosmetics and cosmeceutical products.

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.

Skin: Basic structure and function of skin.

Hair: Basic structure of hair, hair growth cycle.

Oral Cavity: Common problem associated with teeth and gems.

UNIT II

Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.

Anti perspants and Deodrants: Actives and MOA.

Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.

Chemistry and formulation of Para-phylene di amine-based hair dye.

Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III

Sun protection, classification of sunscreens and SPF.

Role of herbs in cosmetics:

Skin care – Aloe and turmeric

Hair care – Henna and amla

Oral care – Clove and neem

Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV

Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.

Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.

Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Industrial Pharmacy)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in differentkinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology forprovide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. BharuchaErach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380013, India,
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Industrial Pharmacy)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to;

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India,
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

PHARMACEUTICAL VALIDATION (Open Elective)

Course Objective: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcome: Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

RECOMMENDED BOOKS:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton &Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Upll, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Chemistry)

NUTRACEUTICALS (Open Elective)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals.

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as neutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims.

RECOMMENDED BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.

3. Advanced Nutritional Therapies by Cooper. K. A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn. Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T. P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T. P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition.Lea and Febiger

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

SCREENING METHODS IN PHARMACOLOGY (Open Elective)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

COSMETIC SCIENCE (Open Elective)

Course Objectives: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcomes: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I
Classification of cosmetics and cosmeceutical products.
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.
Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.
Skin: Basic structure and function of skin.
Hair: Basic structure of hair, hair growth cycle.
Oral Cavity: Common problem associated with teeth and gems.

UNIT II
Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.
Anti-perspirants and Deodorants: Actives and MOA.
Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.
Chemistry and formulation of Para-phylene di amine-based hair dye.
Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III
Sun protection, classification of sunscreens and SPF.
Role of herbs in cosmetics:
Skin care – Aloe and turmeric
Hair care – Henna and amla
Oral care – Clove and neem
Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV
Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V
Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.
Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.
Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.
Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380013, India.
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to;

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcome: On completion of this course it is expected that students will be able to understand;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching And Organizing An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

TEXT AND REFERENCE BOOKS:

1. Akhauri, M. M. P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar (2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

COSMETIC SCIENCE (Open Elective)

Course Objective: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcome: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I

Classification of cosmetics and cosmeceutical products.

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.

Skin: Basic structure and function of skin.

Hair: Basic structure of hair, hair growth cycle.

Oral Cavity: Common problem associated with teeth and gems.

UNIT II

Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.

Anti perspants and Deodrants: Actives and MOA.

Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.

Chemistry and formulation of Para-phylene di amine-based hair dye.

Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III

Sun protection, classification of sunscreens and SPF.

Role of herbs in cosmetics:

Skin care – Aloe and turmeric

Hair care – Henna and amla

Oral care – Clove and neem

Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV

Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.

Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.

Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (PHARMACEUTICAL QUALITY ASSURANCE)

NUTRACEUTICALS (Open Elective)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

b. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
c. Sulfides: Diallylsulfides, Allyltrisulfide.
d. Polyphenolics: Reservetrol
e. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
f. Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
g. Phytoestrogens, Isoflavones, daidzein, Geebustin, lignans
h. Tocopherols

UNIT III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin
c. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

RECOMMENDED BOOKS:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

NANO BASED DRUG DELIVERY SYSTEMS (Open Elective)

Course Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with a
ppropriate technologies, evaluate the product related test and for identified diseases

UNIT I – Introduction to Nanotechnology

a. Definition of nanotechnology
b. History of nanotechnology
c. Unique properties and classification of nanomaterials
d. Role of size and size distribution of nanoparticles properties.
e. Marketed formulations based on nanotechnology and science behind them

UNIT II – Synthesis of Nanomaterials

Physical, chemical and biological Methods
Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferasomes, micelles, aquasomes and nanoemulsions

UNIT III - Biomedical applications of Nanotechnology

a. Nanotechnology products used for in vitro diagnostics
b. Improvements to medical or molecular imaging using nanotechnology
c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

RECOMMENDED BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)

6. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley &Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, AnkaneyuluYerramilli, BS Publications. 2016

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Open Elective)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health careregimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT - I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT - II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT - III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT - IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:
Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and

Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

RECOMMENDED BOOKS:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacology)

COSMETICOLOGY (Open Elective)

Course Objective: This subject will impart knowledge about physiological structure of skin, hair, nail and eye. This gives the information about rheological properties of different cosmetic properties. It will teach the students on preparation and evaluation of different cosmetic products and their excipients. It will teach the students in developing cosmetic safety and new technology in developing cosmetics.

Course Outcome: Upon completion of the course, the student shall be able to,

- Explain the physiological structures of skin, hair, nail and eye.
- It gives the knowledge about rheological property determination
- Explain the evaluation process, safety use of cosmetics and new technology development.
- Explain the principles involved in liposomes, multiple emulsions and creams.

UNIT I

1) Physiological consideration: skin, hair, nail and eye - in relation to cosmetic application.
2) Rheology of cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

UNIT II

3) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics.
4) Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

UNIT III

5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
6) Herbal cosmetics: Formulation development

UNIT IV

7) Packaging: Package development and design for cosmetics including aerosol packs
8) Regulatory requirements: Manufacturing and sale of cosmetics

UNIT V

9) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
10) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

RECOMMENDED BOOKS:

1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
2. J.B. Wilkinson and R.J. Moore; Harry's cosmetology; Longman Science and Technical.
3. S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4. E.G. Thomssen; Modern cosmetics; Universal Publishing Corporation.
5. M.S. Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
6. R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
7. H.R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8. W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.

9. C.G. Gebelein, T.C.Cheng and V.C. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10. L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11. W.A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3, Chapman and Hall
12. Dr.Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacology)

PHARMACEUTICAL ADMINISTRATION (Open Elective)

Course Objective: This subject will provide principles of pharmaceutical industrial management, forms of business organization, plant location and layout. It will teach the students on workman safety, export and import of drugs and pharmaceuticals and briefly on industrial accounting.

Course Outcome: Upon completion of the course, the student shall be able to, Explain the Indian pharmaceutical industry development, knowledge about Pharmaxil and its involvement Explain the books of accounting, journals, ledger, cashbook and balance sheet.

UNIT I
Pharmaceutical Industrial administration: Principles of Pharmaceutical Industrial Management in relation to the Introduction to forms of Business Organization. Manufacturing Management: Plant location, factory building lay-out, production management goals and organization, operating problems, production policy, initiation of production, purchasing and inventory control, works lay-out and plant management.

UNIT II
Workman Safety: measures to health hazards and prevention of environmental pollution. Organization of Distribution and Marketing: Factors in distributions, Sales organization and sales promotions. General principles of medical detailing. Export and Import trade. GATT,WTO- New product development. .

UNIT III
Indian pharmaceutical industry: Pharmaceutical industry in India, milestones in the development of pharmaceutical industry, current status and its role in national economy and national health. Structure of the industry, organized sector, small sector, manufacture of pharmaceuticals in public sector. Progress in the manufacture of basic drugs – synthetic and drugs of vegetable origin.

UNIT IV
Export and import of drugs and pharmaceuticals –knowledge of PHRMEXIL. Various types of insurances including marine insurance. Pharmaceutical associations and societies, statutory councils governing the profession. Principle of Drug store and community pharmacy administration: Drug store management: Drug store planning and lay – out, sales promotion and salesmanship in drug store. Accounting records in drug stores.

UNIT V
Elements of industrial accounting accountancy: Elements of double entry, books of accounts, journal, ledger and cashbook. The balance sheet, profit and loss account. Principles of costing and estimating.

RECOMMENDED BOOKS:

1. Essentials of management by Dr.Herold Koontz and Heinz Weitnrich, published by McGraw Hill publishing company.
2. Managing productivity in organizations by Kopelman, published by McGraw Hill publishing company.
3. Effective supervision: A practical approach by Hodgetts, published by McGraw Hill publishing company.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacology)

DRUG REGULATORY AFFAIRS (Open Elective)

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I
Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC& BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II
Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety. (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III
A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV
Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V
Governing Regulatory Bodies across the globe.
Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product DirectorateDMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    3) MHRA – Medicines and Health Care Products Regulatory Agency
d. Product Filing

e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

RECOMMENDED BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacology)

PROJECT MANAGEMENT (Open Elective)

Course Objective: This subject will provide introduction of project life cycle, its duties, planning for project life cycle leaders and their involvement project management. It will teach the students on role of project managers, clients, customers etc. This subject also focuses on project planning process, executing and heading the project team and responsibilities.

Course Outcome: Upon completion of the course, the student shall be able to,

- Explain the project management and its life cycle
- Involves in different duties as project manager, clients and customers
- Explain the responsibilities of key players involved in project management
- Execute project as project leaders and team responsibilities.

UNIT I
Introduction & Project Life Cycle
The difference between a project manager and a project engineer / project leader, duties of a project engineer /project leader, relationship between scope/schedule/budget/resources and how it relates to all project activities
Project Life Cycle and how it relates to project definition and control, feasibilities and feasibility study, key elements of working in a group and group dynamics.

UNIT II
Pre-Planning for Project Management:
Importance of project management, organizing for project management, Role of project manager, Role of clients, customers and others, setting up planning and control system.

UNIT III
Project Planning Process:
Defining project, creating work breakdown structure, estimating activities, sequencing activities, calculating the critical path, scheduling project, resources planning, preparing planning budgets, approval of projects, setting up a monitoring and control process.

UNIT IV
Executing the Project
Initiating the project, controlling project objectives, reporting on project objectives, controlling changes in the project, conducting project evaluations, managing risks in project management,
Closing the project.

UNIT V
Heading the Project Team
Developing project teams, managing conflicts, communicating effectively, holding effective meetings, making team decisions, using sources of power wisely, making changes, managing performance

RECOMMENDED BOOKS:

1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
2. Project management: The managerial process By Clifford F. Gray and Eric W. Larson Publisher: Tata Mc Graw Hill Third edition
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
4. Project management By Jeffery K. Pinto Publisher: Prentice-Hall Year of publication 2007.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacology)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)

SCREENING METHODS IN PHARMACOLOGY (Open Elective)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objectives: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes: On completion of this course it is expected that students will be able to;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

RECOMMENDED BOOKS:

1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)

COSMETIC SCIENCE (Open Elective)

Course Objectives: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcomes: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I
Classification of cosmetics and cosmeceutical products.
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.
Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.
Skin: Basic structure and function of skin.
Hair: Basic structure of hair, hair growth cycle.
Oral Cavity: Common problem associated with teeth and gems.

UNIT II
Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.
Anti perspants and Deodrants: Actives and MOA.
Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.
Chemistry and formulation of Para-phylene di amine-based hair dye.
Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III
Sun protection, classification of sunscreens and SPF.
Role of herbs in cosmetics:
Skin care – Aloe and turmeric
Hair care – Henna and amla
Oral care – Clove and neem
Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV
Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V
Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.
Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.
Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.

Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)

HAZARDS AND SAFETY MANAGEMENT (Open Elective)

Course Objectives: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle-based approach to solve the complex tribulations.

Course Outcomes: At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in differentkinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology forprovide safe industrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, Human and health safety measures.

a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system:

Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention,

elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment
procedure, Role of emergency services.

RECOMMENDED BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Safety and Health in Industry: A Handbook by AM Sarma, Pharmamed Press
4. Occupational Hazards Safety and Environmental Studies by A M Sarma Pharmamed Press
5. Occupational Health and Hygiene in Industries, Raja Sekhar Mamillapalli, Visweswara Rao
6. BharuchaErach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380013, India,
7. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmaceutical Analysis)

AUDITS AND REGULATORY COMPLIANCE (Open Elective)

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcome: Upon completion of this course the student should be able to

- To understand the importance ofauditing
- To understand the methodology ofauditing
- To carry out the auditprocess
- To prepare the auditingreport
- To prepare the check list forauditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press.2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacognosy)

SCREENING METHODS IN PHARMACOLOGY (Open Elective)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springerverlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Guidelines and Screening Methods of Pharmacology, Surendra H. Bodakhe, Pharmamed Press

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacognosy)

COSMETIC SCIENCE (Open Elective)

Course Objective: These topics are designed impart a specialized knowledge to know various cosmetics, their preparation, properties, MOA, uses etc. The understanding of properties and evaluation of these cosmetics by analytical methods.

Course Outcome: The students should describe the properties and uses of various cosmetics on various parts of the body. The students should be able to suggest the proper usage of cosmetics.

UNIT I

Classification of cosmetics and cosmeceutical products.

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives, classification and application.

Skin: Basic structure and function of skin.

Hair: Basic structure of hair, hair growth cycle.

Oral Cavity: Common problem associated with teeth and gems.

UNIT II

Principles of formulation and building blocks of skin care products: Face cream, Moisturizing cream, Cold cream, Vanishing cream and their advantages and dis advantages. Application of these products in formulation of cosmeceuticals.

Anti perspants and Deodrants: Actives and MOA.

Principles of formulation and building blocks of hair care products: Conditioning shampoo, hair conditioner, anti – dandruff shampoos, hair oils.

Chemistry and formulation of Para-phylene di amine-based hair dye.

Principles of formulation and building blocks of oral care products: Tooth paste for bleeding gums, sensitive teeth, teeth whitening, mouth wash.

UNIT III

Sun protection, classification of sunscreens and SPF.

Role of herbs in cosmetics:

Skin care – Aloe and turmeric

Hair care – Henna and amla

Oral care – Clove and neem

Analytical Cosmetics: BIS specification and analytical method for shampoo, skin cream and tooth paste.

UNIT IV

Principle of cosmetic evaluation – Principle of sebumeter, corneometer. Measurement of tewl, skin color, hair tensile strength, hair combing properties. Soaps and Syndet bars, evaluation and skin benefits.

UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic, dermatitis.

Cosmetic problems associated with hair and scalp: Dandruff, hair fall causes.

Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor.

Anti-perspirants and deodorants – Actives and MOA

RECOMMENDED BOOKS:

1. Harry's cosmeticology, Wilkinson, Moore, 7th edition, George Godwin.
2. Cosmetics – Formulation, Manufacturing and Quality control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd. Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacognosy)

NUTRACEUTICALS (Open Elective)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:

Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

i. Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
j. Sulfides: Diallylsulfides, Allyltrisulfide.
k. Polyphenolics: Reservetrol
l. Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
m. Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
n. Phytoestrogens, Isoflavones, daidzein, Geebustin, lignans
o. Tocopherols

UNIT III

c. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
d. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

d. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
e. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin
f. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

RECOMMENDED BOOKS:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm II Year I Sem (Pharmacognosy)

ENTREPRENEURSHIP MANAGEMENT (Open Elective)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcome: On completion of this course it is expected that students will be able to understand;

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching And Organizing An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

TEXT AND REFERENCE BOOKS:

1. Akhauri, M. M. P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad Ed II.
6. Arya kumar (2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson.