



# AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES

(Approved by PCI, AICTE & Affiliated to JNTUH)

Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Ramoji Filmcity, Hyderabad - 501 512.



### 3.1.1. Grants received from Government and non-governmental agencies for research projects, endowments in the institution during the years 2022-2023.

S.NO	NAME OF THE PROJECT INVESTIGATOR/Chief Investigator	NAME OF THE FUNDING AGENCY	FUND PROVIDED(INR IN LAKHS)	DURATION OF THE PROJECT
1	1. Dr.K.Balaji 2. Dr. Nihar Ranjan Das 3. Dr. B.Manjula	INCEPTION SOURCE	4.00	6 MONTHS
2	1. Dr.K.Balaji 2. Dr. Nihar Ranjan Das 3. Dr. B.Manjula	CLINOXY SOLUTIONS PVT LTD	1.00	6 MONTHS

  
PRINCIPAL  
AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES  
Gunthapally (V), Abdullapurmet (M),  
R.R. Dist. Telangana.



Date: 18/07/2022  
Hyderabad

To  
The Principal  
Avanthi Institute of Pharmaceutical sciences,  
Gunthapally (v), Abdullapurmet (M).

Dear Sir,

Sub: Looking for a qualified team who can work for our Organization's Project

Inception Sources Pvt Ltd is an expert strategic developer and commercialization global partner for pharmaceutical, biotechnology and medical device industries. Inception Sources Pvt Ltd experienced Employees, well established programs and processes bring a new dimension to development strategy, regulatory submissions, clinical research, consumer health care, medical and scientific support.

We are looking for a team of qualified faculty members at your college in Pharmacy Department who can work on Effect of Polymer Concentration on Drug Release in the Formulation Controlled Release Tablets of Glipizide Using Various Polymers If your college is interested to work in collaboration. We forward further documentation & I sincerely hope that we can keep the information confidential.

Looking forward & thank you.

Managing Director



**Inception Source Pvt. Ltd.**

Branch office 1: H. No: 11-13-1427, 2nd Floor, Nirmal Sadan, Kothapet Hyderabad - 35

Branch office 2: H. No: 5-5-35, 2nd floor, Prashanthi nagar, Hyderabad - 500072

✉ info@inceptionsource.in | 🌐 www.inceptionsource.in | ☎ +91 99639 85925



**AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES**

(Approved by PCI, AJCTE & Affiliated to JNTUH)

Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Rameji Filicity, Hyderabad - 501 512.



Date: 19/07/2022

Hyderabad

To  
The Manager  
Inception Sources,

From  
The principal,  
Avanthi Institute of Pharmaceutical Sciences,  
Gunthapally (v)  
Respected Sir / Madam,

We thank you for sharing us the proposed project details.

In this regard, we are happy to inform that our institution is having all the technical resources in terms of Infrastructure and Skilled resources. We are also having faculty members in the specialization required.

We are ready to submit a detailed project proposal with all necessary details upon confirmation from your end.

Thank you once again.

Yours Sincerely

Principal

- PRINCIPAL

Avanthi Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



Copy to:

1. HOD of Pharmacy
2. Principal Office
3. File



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Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Ramoji Filmcity, Hyderabad - 501 512.



Date: 19/07/2022

From  
The Principal  
Avanthi Institute of Pharmaceutical sciences,  
Gunthapally (v), Abdullapurmet (M)

To  
The Managing Director,  
Inception Sources Pvt Ltd,  
Hyderabad,

Respected sir,

Sub: Project Development-Acceptance Reg...

It gives us great pleasure to let you know that the project proposal for "Effect of Polymer Concentration on Drug Release in the Formulation Controlled Release Tablets of Glipizide Using Various Polymers" has been confirmed. As we discussed in our conversation, we agreed to maintain the confidentiality of the Project. We appreciate you giving us the opportunity to work on your current project, which has to do with the most recent developments in the design sector. The following is the list of faculty members allotted

1. Dr.K.Balaji
2. Dr. Nihar Ranjan Das
3. Dr. B.Manjula

Please be assured that we will make every effort to complete the project as quickly as we can.

Thanking you,

Copy to:

1. HOD of Pharmacy
2. Principal Office
3. File



Principal  
Avanthi Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.






**Financial requirement (all figure must be INR)**

S. No	Item Head	Total (in Lakh)
<b>Capital Component</b>		
1	Permanent Equipment (Located in lab/implementing organization) as per billing	3,00,000
2	demonstration chemicals (located at beneficiary location)	60,000/-
A	Subtotal (Capital Items)	3,60,000/-
<b>General Component</b>		
1	Manpower and Contingencies	10,000/-
2	Non Consumables	10,000/-
3	Travel	10,000/-
4	Overhead	-----
5	PC	-----
6	Printer and Scanner	10,000/-
B	Subtotal (General)	40,000/-
C	<b>Total cost of the project (A+B)</b>	<b>4,00,000/-</b>

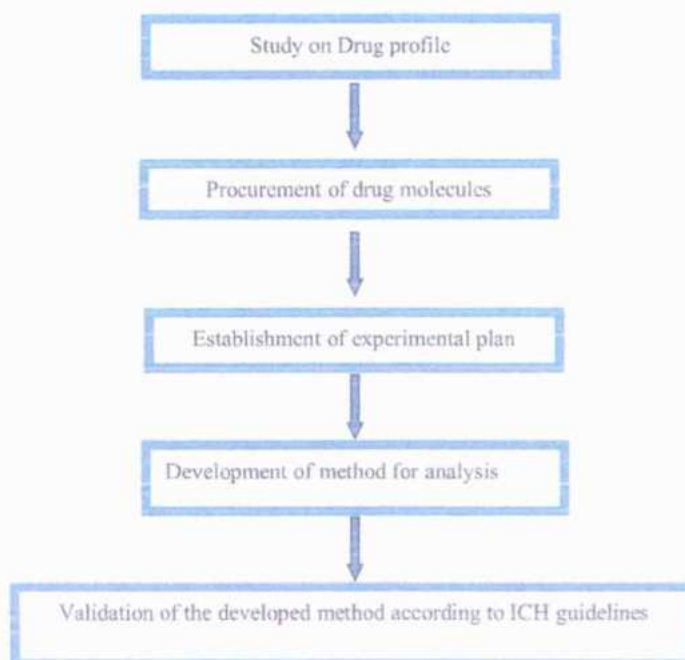
- I. Project Cost: 4,00,000/-
- II. Contribution of consortium (if any):
- III. Total Budget (I+II): 4,00,000/-



  
Avanathi Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



## FLOWCHART OF PROJECT PROCEDURE:



The study deals with the new stability indicating method development and validation for the simultaneous determination of Diacerin, Glucosamine sulphate and Methyl sulfonyl methane by RP-HPLC.


### Objectives:

- To develop an RP-HPLC method with a PDA detector for the simultaneous separation and quantification of selected drugs.
- The method is validated in accordance with ICH guidelines and can be used effectively for Quality control.
- To perform forced degradation studies in various conditions like acid, alkali, and oxidation, thermal, neutral and photo stability.

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**Avanthi Institute of Pharmaceutical Sciences**



  
PRINCIPAL  
AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES  
Gunthapally (V), Abdullapurmet (M)  
R.R. Dist. Telangana.

**WORK ORDER**

Date: 26/07/2022

WO NO: WO/ISPL/2022-23/CO1

HYDERABAD

To  
The Principal  
Avanthi Institute of Pharmaceutical Sciences  
Gunthapally  
Abdullapurmet Mandal  
Hyderabad

Sub: Request-Method Development and Validation of Active Pharmaceutical Ingredients-Reg.....

Further to your offer for the Validation of Developed method as per the Discussion quotation, we are pleased to place the work order as below

S.NO	Description	Quantity in no	Unit Cost Rs.
1	Procurement of Dosage materials	1	20,000
2	Chemicals ,Reagents & Solvents	3	20,000
3	Equipments & Glassware	2	3,00,000
4	Compounds Characterization	4	20,000
5	Pharmacological evaluation	1	40,000
6	Total Cost in rupees		4,00,000/-

Rupees in words: Four lakhs Rupees only

Work Oder Valid: One Year (FROM 26/07/2022 TO 25/07/2023)

**Terms& Conditions:**

- Preparation of detailed pharmaceutical dosages, analysis based on the reference provided by the customer.
- Submission of analysis/lay outs for review and approval of our customer
- Incorporate any comments/feed back given by customer for drug.
- Preparation of built up designs, analysis after completion of fabrication/Installation at site.

**WORKING LOCATION:** You're Premises

For Inception Sources Pvt Ltd

PURCHASE MANAGER





**Inception Source Pvt. Ltd.**

Branch office 1: H. No: 11-13-1427, 2nd Floor, Nirmal Sadan, Kothapet Hyderabad - 35

Branch office 2: H. No: 5-5-35, 2nd floor, Prashanthi nagar, Hyderabad - 500072

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Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Rameji Filmcity, Hyderabad - 501 512.



Date: 27/07/2022

From  
The Principal  
Avanthi Institute of Pharmaceutical sciences,  
Gunthapally (v), Abdullapurmet (M).

To  
The Managing Director,  
Inception Sources Pvt Ltd,  
Hyderabad,

Respected sir,

Sub: Effect of Polymer Concentration on Drug Release in the Formulation Controlled Release Tablets of Glipizide Using Various Polymers

It gives us great pleasure to let you know that the project proposal for "Effect of Polymer Concentration on Drug Release in the Formulation Controlled Release Tablets of Glipizide Using Various Polymers" has been confirmed. As we discussed in our conversation, we agreed to maintain the confidentiality of the Project. We appreciate you giving us the opportunity to work on your current project, which has to do with the most recent developments in the design sector. It gives great pleasure to allot the project development team.

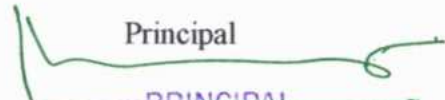
Please be assured that we will make every effort to complete the project as quickly as we can.

Thanking you Sir,

Copy to:

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3. File



Principal  
  
PRINCIPAL  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.





**AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES**

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Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Ramoji Filmcity, Hyderabad - 501 512.



Date: 26/01/2023  
Hyderabad

From  
The principal,  
Avanthi Institute of Pharmaceutical Sciences,  
Gunthapally (v)

To  
Proprietor,  
Inception Sources Pvt Ltd  
Hyderabad,

Respected Sir,


Sub: Project Completion-reg.

The project has been completed on a given time bond. It has been a great achievement by us to complete the prestigious project on time. It has been a great privilege, working in association with you and looking forward to working with you in future projects. We request you to please come along with your team for collecting, retrieving of important and confidential data.

Looking forward to a quick response from your side.

Thanking you,



  
Principal  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



## PROJECT REPORT:

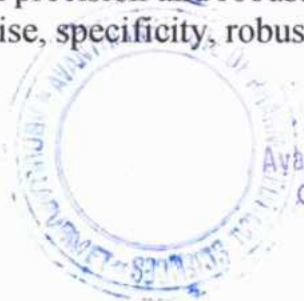
### Introduction:

A controlled release drug delivery system delivers the drug locally or systemically at a predetermined rate for a specified period of time the goal of such systems is to provide desirable delivery profiles that can achieve therapeutic plasma levels. Drug release is dependent on polymer properties, thus the application of these properties can produce well characterized and reproducible dosage forms.<sup>6</sup>

The basic rationale of a controlled release drug delivery system is to optimize the bio pharmaceutics, pharmacokinetics, and pharmaco dynamics properties of a drug in such a way that its utility is maximized through reduction in side effects and cure or control of disease condition in the shortest possible time by using smallest quantity of drug, administered by most suitable route. The immediate release drug delivery system lacks some features like dose maintenance, controlled release rate and

### Scope of the Project:

A stability indicating RP-HPLC method was developed and validated for the estimation of Emtricitabine (EMT), Rilpivirine (RIL), and Tenofovir Alafenamide (TAF) in combined dosage forms and its API. Chromatographic separation of these drugs was performed on INERTSIL column, C18 (150x4.6 ID) 5 $\mu$ m as the stationary phase using solvent system consisted of Phosphate buffer: Acetonitrile 40:60. The method was validated according to the International Conference of Harmonization (ICH) guidelines. The method showed accuracy of 100.19%, 101.30% and 99.70% and percentage Assay of 100.04%, 99.74% and 102.14% for Emtricitabine, Rilpivirine and Tenofovir Alafenamide, respectively. Percentage relative standard deviation (<2%) was found for both precision and robustness study showing that the Proposed method was precise, specificity, robust and stable in accordance with ICH guidelines.



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## Project planning and scheduling:

Evaluation of post compression parameters for prepared Tablets

The designed formulation tablets were studied for their physico-chemical properties like weight variation, hardness, thickness, friability and drug content.

Weight variation test:

To study the weight variation, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviate by more than twice the percentage. The mean and deviation were determined. The percent deviation was calculated using the following formula.

$$\% \text{ Deviation} = (\text{Individual weight} - \text{Average weight} / \text{Average weight}) \times 100$$

### Data collection and Analysis:

1. Pre formulation parameters Angle of repose:

The angle of repose was calculated using the following formula:

$$\tan \theta = h/r \quad \tan \theta = \text{Angle of repose}$$

h = Height of the cone, r = Radius of the cone base

Bulk density:

The bulk density was calculated using the formula: Bulk Density =  $M / V_0$

Where,

M = weight of sample

$V_0$  = apparent volume of powder

Tapped density:

The tapped density was calculated, in gm per L, using the formula:

Tap =  $M/V$  Where,

Tap = Tapped Density M = Weight of sample

V = Tapped volume of powder



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Avanthi Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



### Measures of powder compressibility:

For poorer flowing materials, there are frequently greater inter particle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

Carr's Index =  $[(\text{tap}-b)/\text{tap}] \times 100$  Where, b = Bulk Density  
Tap = Tapped Density

### Formulation development of Tablets:

All the formulations were prepared by direct compression. The tablets were prepared as per the procedure given below and aim is to prolong the release of Glipizide

### Methodology

#### Analytical method development:

a) Determination of absorption maxima:

10mg of Glipizide pure drug was dissolved in 10ml of Methanol (stock solution). 1ml of above solution was taken and made up to 10ml by using 0.1 N HCl (100 $\mu$ g/ml). From this 1ml was taken and made up to 10ml of 0.1 N HCl (10 $\mu$ g/ml) and the solution was scanned in the range of 200–400nm. Similar procedure was repeated to pH 6.8 Phosphate buffer UV spectrum was taken using Double beam UV/VIS spectrophotometer.

b) Preparation calibration curve:

10mg of Glipizide pure drug was dissolved in 10ml of Methanol (stock solution). 1ml of above solution was taken and made up to 10ml by using 0.1 N HCl (100 $\mu$ g/ml). From this 1ml was taken and made up to 10ml of 0.1 N HCl (10 $\mu$ g/ml). The above solution was subsequently diluted with 0.1N HCl to obtain series of dilutions containing 10, 20, 30, 40 and 50 $\mu$ g/ml of Glipizide per ml of solution. The absorbance of the above dilutions was measured at 255nm by using UV- Spectrophotometer taking 0.1N HCl as blank.



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Ranga Reddy Dist.





### Resources and budget allocation:

It will provide an overview of the resources allocated to the project, including human resources, consumables, techniques, laboratory facilities, contingencies and other project expenses. A detailed budget estimate will be presented considering the costs associated with development of new drug molecule.

### Documentation and record keeping:

The outline and the documentation practices employed throughout the project. Proper documentation will facilitate traceability and aid future reference.

### Conclusion:

A simple, rapid, accurate, and precise stability-indicating HPLC analytical method had been developed and validated for the routine simultaneous estimation of EMT, RIL, and TAF in API and tablet dosage forms. The RT of EMT, RIL, and TAF using optimum conditions was 2.517, 3.273, and 6.697 min, respectively. The simplicity of the HPLC procedure, the short runtime, and the low volume of injection make this method suitable for quick and routine analysis. The stability indication nature of the analytical method provides confidence to use the developed method in a regulatory environment of the pharmaceutical industry without any further modification.

PROJECT INVESTIGATOR

PRINCIPAL



- PRINCIPAL  
Avanthi Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



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## UTILIZATION CERTIFICATE

Academic Year: 2022-23

Certified that the grant of Rs. 4, 00,000 received to Avanthi Institute of Pharmaceutical sciences under the funding agency, for the Research Project entitled " Effect Of Polymer Concentration On Drug Release In The Formulation Controlled Release Tablets Of Glipizide Using Various Polymers" has been fully utilized for the purpose for which it was sanctioned and in accordance with in terms and conditions laid down in R&D policy of the institute. I have successfully published the paper J.Pharm. Sci. &Res.Vol.13 (3), 2021, 162-169



Sign of the Project Investigator  
Department of Pharmacy

- PRINCIPAL  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.

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05022023

D D M M Y Y Y Y

अदा करे Avanthi Institute of Pharmacy/ Sciences

or Bearer

पेस रुपये Four lakhs rupees only

₹ 4,00,000/-

Ac No 1456135000005823

INITIAL

FOR INCEPTION SOURCE PRIVATE LIMITED

DIRECTOR(S) AUTHORIZED SIGNATORY

000203 5000530101 001776 29





**AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES**

Joint Holder :-  
GUNTHAPALLY(V) HAYATH NAGAR MANDAL  
RANGAREDDI CITY- RANGA REDDY  
NEAR RAMOJI FILM CITY  
RANGAREDDY  
TELANGANA-INDIA  
501512

Customer ID :879983002  
IFSC Code :UTIB0002738  
MICR Code :500211055  
Nominee Registered : N

Registered Mobile No :XXXXXX5659  
Registered Email ID:  
Scheme :SB-TRUST/SOCIETY/NGO/GOVT

PAN :AAATA3530B

**Statement of Axis Account No :918010020435948 for the period (From : 16-02-2023 To : 17-02-2023)**

Tran Date	Chq No	Particulars	Debit	Credit	Balance	Init. Br
		<b>OPENING BALANCE</b>			<b>4725309.13</b>	
16-02-2023		IFT/011602234647/1	4000000.00		725309.13	2738
16-02-2023		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 15.02.		2500.00	727809.13	274
17-02-2023		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 16.02.		20000.00	747809.13	274
17-02-2023		TRF/INCEPTION SOURCE PRIVATE LIMITED/		400000.00	1147809.13	1456
17-02-2023		TRF/DESATLA SHEKAR/CLINOXY SOLUTIONS PVT/LTD/		100000.00	1247809.13	4267
		<b>TRANSACTION TOTAL</b>	<b>4000000.00</b>	<b>522500.00</b>		
		<b>CLOSING BALANCE</b>			<b>1247809.13</b>	

Unless the constituent notifies the bank immediately of any discrepancy found by him/her in this statement of Account, it will be taken that he/she has found the account correct.

The closing balance as shown/displayed includes not only the credit balance and / or overdraft limit, but also funds which are under clearing. It excludes the amount marked as lien, if any. Hence the closing balance displayed may not be the effective available balance. For any further clarifications, please contact the Branch.

We would like to reiterate that, as a policy, Axis Bank does not ask you to part with/disclose/revalidate of your iConnect passord,login id and debit card number through emails OR phone call Further,we would like to reiterate that Axis Bank shall not be liable for any losses arising from you sharing/disclosing of your login id, password and debit card number to anyone. Please co-operate by forwarding all such suspicious/spam emails, if received by you, to customer.service@axisbank.com

With effect from 1st August 2016, the replacement charges for Debit card and ATM card applicable on Current accounts have been revised. To know more about the applicable charges,please visit www.axisbank.com

Deposit Insurance and Credit Guarantee Corporation (DICGC) insurance cover is applicable in all Banks' deposits, such as savings, current, fixed, recurring etc\* up to maximum amount of Rs 5 Lakh including principal & interest both\* (\* or exceptions and details please refer www.dicgc.org.in )

In compliance with regulatory guidelines, the non-CTS cheque books attached to the accounts would be destroyed in banks core banking System. Thus, Non CTS cheques will not be valid for CASH, Clearing and Transfer transactions

REGISTERED OFFICE - AXIS BANK LTD,TRISHUL,Opp. Samartheswar Temple, Near Law Garden, Ellisbridge, Ahmedabad . 380006.This is a system generated output and requires no signature.

BRANCH ADDRESS - AXIS BANK LTD, VANASTHALIPURAM HYD TG, DOOR NO 5-5-1189, SY NO.15(P), PLOT NO 2/A & 3/B, SAHEB NAGAR, KURD,HAYATHNAGAR(M), LB NAGAR CIRCLE III, 500070, HYDERABAD, TELANGANA, INDIA, TEL:040-24113411 FAX:

**Legends :**

- ICONN - Transaction trough Internet Banking
- VMT-ICON - Visa Money Transfer through Internet Banking
- AUTOSWEEP - Transfer to linked fixed deposit
- REV SWEEP - Interest on Linked fixed Deposit
- SWEEP TRF - Transfer from Linked Fixed Deposit / Account
- VMT - Visa Money Transfer through ATM
- CWDR - Cash Withdrawal through ATM
- PUR - POS purchase





## CLINOXY SOLUTIONS PRIVATE LIMITED

CIN (U74910TG2021PTC155213)

Date: 18/07/2022  
Hyderabad

To  
The Principal  
Avanthi Institute of Pharmaceutical sciences,  
Gunthapally (v), Abdullapurmet (M)


Dear Sir,

Sub: Looking for a qualified team who can work for our Organization's Project

CLINOXY is an expert strategic developer and commercialization global partner for pharmaceutical, biotechnology and medical device industries. CLINOXY experienced Employees well established programs and processes bring a new dimension to development strategy, regulatory submissions, clinical research, consumer health care, medical and scientific support.

We Endeavour to provide best value services and solutions that place the highest priority on creative excellence and efficiency. For aspiring Pharmacy researchers to catalyze & support research development and adaptation of need —based technologies to address the identified societal challenges. We are looking for a team of qualified faculty members at your college in Pharmacy Department who can work on “Development of New Analytical Method and Validation of Anti-Neoplastic Agents Netupitant and Palonosetron in Pure and Pharmaceutical Formulation by Rp-Hplc” analytical research and development and formulation research and development. If your college is interested to work in collaboration. We forward further documentation & I sincerely hope that we can keep the information confidential.

Looking forward & thank you.

  
Managing Director



Phone: +91 94925 11123  
Email: [clinoxysolutions@gmail.com](mailto:clinoxysolutions@gmail.com)  
[info@clinoxy.com](mailto:info@clinoxy.com)

Address: KPHB 9<sup>th</sup> Phase, Hyderabad  
Telangana. 500085  
website: [www.clinoxy.com](http://www.clinoxy.com)



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Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Rameji Filmcity, Hyderabad - 501 512.



Date: 19/07/2022  
Hyderabad

To  
The Manager  
Clinoxy solutions Pvt Ltd,

From  
The principal,  
Avanthi Institute of Pharmaceutical Sciences,  
Gunthapally (v)

Respected Sir / Madam,

We thank you for sharing us the proposed project details.

In this regard, we are happy to inform that our institution is having all the technical resources in terms of Infrastructure and Skilled resources. We are also having faculty members in the specialization required.

We are ready to submit a detailed project proposal with all necessary details upon confirmation from your end.

Thank you once again.

Yours Sincerely

Principal

Copy to:

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3. File



- PRINCIPAL  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



Date: 19/07/2022

From,  
The Principal  
Avanthi Institute of Pharmaceutical sciences,  
Gunthapally (v), Abdullapurmet (M).

To  
The Managing Director,  
Clinoxy solutions Pvt Ltd,  
Hyderabad,

Respected sir,

Sub: Project Development-Acceptance Reg...

It gives us great pleasure to let you know that the project proposal for "Development of New Analytical Method and Validation of Anti-Neoplastic Agents Netupitant and Palonosetron in Pure and Pharmaceutical Formulation by Rp-Hplc" has been confirmed. As we discussed in our conversation, we agreed to maintain the confidentiality of the Project. We appreciate you giving us the opportunity to work on your current project, which has to do with the most recent developments in the design sector. It gives great pleasure to depute project development team. The following are the list of faculty members allotted as given below.

1. Dr.K.Balaji (Project Investigator)
2. Dr. Nihar Ranjan Das (Chief Investigator)
3. Dr. B.Manjula (Technical Advisor)

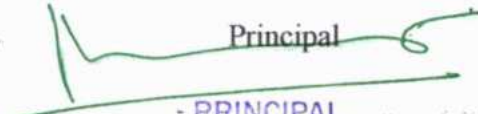
Please be assured that we will make every effort to complete the project as quickly as we can.

Thanking you,

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Principal  
- PRINCIPAL  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.






**Financial requirement (all figure must be INR)**

S. No	Item Head	Total (in Lakh)
<b>Capital Component</b>		
1	Permanent Equipment (Located in lab/implementing organization) as per billing	40,000
2	demonstration chemicals (located at beneficiary location)	30,000/-
A	Subtotal (Capital Items)	70,000/-
<b>General Component</b>		
1	Manpower and Contingencies	10,000/-
2	Non Consumables	10,000/-
3	Travel	5,000/-
4	Overhead	-----
5	PC	-----
6	Printer and Scanner	5,000/-
B	Subtotal (General)	30,000/-
C	<b>Total cost of the project (A+B)</b>	<b>1,00,000/-</b>

- I. Project Cost: 1,00,000/-
- II. Contribution of consortium (if any):
- III. Total Budget (I+II): 1,00,000/-

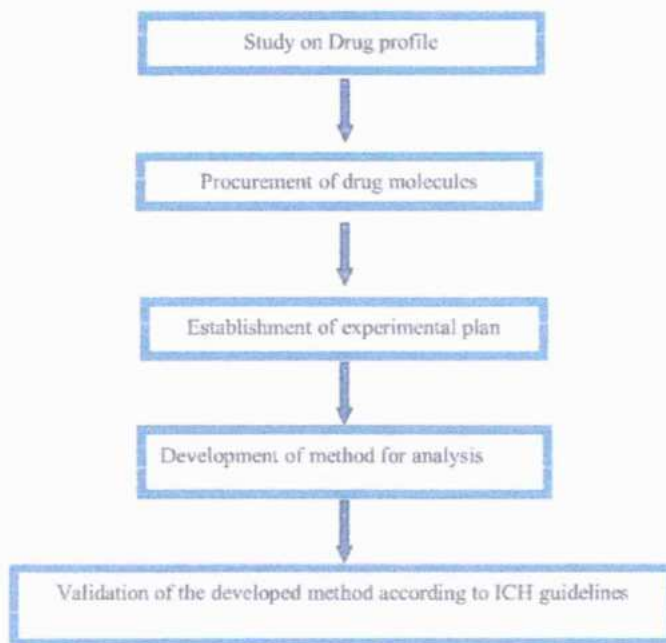


  
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Ranga Reddy Dist.





**FLOWCHART OF PROJECT PROCEDURE:**



The study deals with the new stability indicating method development and validation for the simultaneous determination of Diacerein, Glucosamine sulphate and Methyl sulfonyl methane by RP-HPLC.

**Objectives:**

- To develop an RP-HPLC method with a PDA detector for the simultaneous separation and quantification of selected drugs.
- The method is validated in accordance with ICH guidelines and can be used effectively for Quality control.
- To perform forced degradation studies in various conditions like acid, alkali, and oxidation, thermal, neutral and photo stability.



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# CLINOXY SOLUTIONS PRIVATE LIMITED

CIN (U74910TG2021PTC155213)

**WORK ORDER**

Date: 26/07/2022

WO NO: WO/CSPL/2020-21/CO1

Hyderabad

To  
The Principal  
Avanhi Institute of Pharmaceutical Sciences  
Gunthapally  
Abdullapurmet Mandal  
Hyderabad

Sub: Request-Method Development and Validation of Active Pharmaceutical Ingredients-Reg.

Further to your offer for the Validation of Developed method as per the Discussion quotation, we are pleased to place the work order as below

S.NO	Description	Quantity in no	Unit Cost Rs.
1	Chemicals ,Reagents & Solvents	1	30,000
2	Equipments & Glassware	1	40,000
3	Pharmacological evaluation	1	30,000
4	Total Cost in rupees		1,00,000/-

Rupees in words: One lakh Rupees only

Work Oder Valid: One Year (From 26/07/2022 to 26/07/2023)

**Terms& Conditions:**

- Preparation of detailed pharmaceutical dosages, analysis based on the reference provided by the customer.
- Submission of analysis/lay outs for review and approval of our customer
- Incorporate any comments/feed back given by customer for drug.
- Preparation of built up designs, analysis after completion of fabrication/Installation at site.

**WORKING LOCATION:** You're Premises

For Clinoxy Solutions Pvt Ltd

PURCHASE MANAGER



Phone: +91 94925 11123  
Email: [clinoxysolutions@gmail.com](mailto:clinoxysolutions@gmail.com)  
[info@clinoxy.com](mailto:info@clinoxy.com)

Address: KPHB 9<sup>th</sup> Phase, Hyderabad  
Telangana. 500085  
website: [www.clinoxy.com](http://www.clinoxy.com)



**AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES**

(Approved by PCI, AICTE & Affiliated to JNTUH)

Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Ramoji Filmcity, Hyderabad - 501 512.



Date: 27/07/2022

From,  
The Principal  
Avanthi Institute of Pharmaceutical sciences,  
Gunthapally (v), Abdullapurmet (M).

To  
The Managing Director,  
Clinoxy solutions Pvt Ltd,  
Hyderabad,

Respected sir,

Sub: Development of New Analytical Method and Validation of Anti-Neoplastic Agents Netupitant and Palonosetron in Pure and Pharmaceutical Formulation by Rp-Hplc

It gives us great pleasure to let you know that the project proposal for "Development of New Analytical Method and Validation of Anti-Neoplastic Agents Netupitant and Palonosetron in Pure and Pharmaceutical Formulation by Rp-Hplc" has been confirmed. As we discussed in our conversation, we agreed to maintain the confidentiality of the Project. We appreciate you giving us the opportunity to work on your current project, which has to do with the most recent developments in the design sector.


Please be assured that we will make every effort to complete the project as quickly as we can.

Thanking you Sir,

Copy to:

1. HOD of Pharmacy
2. Principal Office
3. File



  
Principal  
- PRINCIPAL  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.



**AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES**

(Approved by PCI, AICTE & Affiliated to JNTUH)

Gunthapally (V), Abdullapurmet (M), R.R. Dist., Near Ramoji Filmcity, Hyderabad - 501 512.



Date: 26/01/2023  
Hyderabad

From  
The principal,  
Avanthi Institute of Pharmaceutical Sciences,  
Gunthapally (v)

To  
Proprietor,  
Clinoxy solutions Pvt Ltd,  
Hyderabad,

Respected Sir,

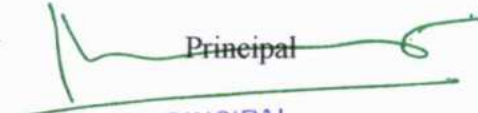
Sub: Project Completion-reg.

The project has been completed on a given time bond. It has been a great achievement by us to complete the prestigious project on time. It has been a great privilege, working in association with you and looking forward to working with you in future projects. We request you to please come along with your team for collecting, retrieving of important and confidential data.

Looking forward to a quick response from your side.

Thanking you,



  
Principal  
- PRINCIPAL  
Avanthi's Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.





## PROJECT REPORT:

### Introduction:

A controlled release drug delivery system delivers the drug locally or systemically at a predetermined rate for a specified period of time. The goal of such systems is to provide desirable delivery profiles that can achieve therapeutic plasma levels. Drug release is dependent on polymer properties, thus the application of these properties can produce well characterized and reproducible dosage forms. Netupitant (NTP) is an ovulate metic[1,2] drug in the combination of NTP/ Palonosetron (PLS). It is used to the prevention of acute and delayed chemotherapy-induced nausea and vomiting [include in highly emetogenicity and chemotherapy such as with cisplatin hydroxytryptamine (5-HT<sub>3</sub>) receptor are located on the nerve

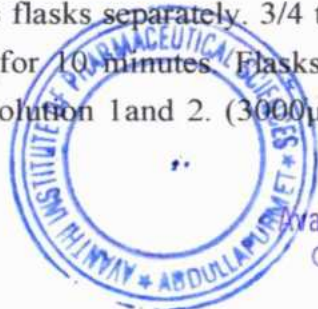
### Scope of the Project:

A stability indicating various polymers was developed and validated for the estimation of Emtricitabine (EMT), Rilpivirine (RIL), and Tenofovir Alafenamide (TAF) in combined dosage forms and its API. Chromatographic separation of these drugs was performed on INERTSIL column, C18 (150x4.6 ID) 5 $\mu$ m as the stationary phase using solvent system consisted of Phosphate buffer: Acetonitrile 40:60. The method was validated according to the International Conference of Harmonization (ICH) guidelines. The method showed accuracy of 100.19%, 101.30% and 99.70% and percentage Assay of 100.04%, 99.74% and 102.14% for Emtricitabine, Rilpivirine and Tenofovir Alafenamide, respectively. Percentage relative standard deviation (<2%) was found for both precision and robustness study showing that the

### Project planning and scheduling:

Preparation of Standard stock solutions

Accurately weighed 150 mg of Netupitant, 0.25mg of Palonosetron and transferred to individual 50 ml volumetric flasks separately. 3/4 th of diluents was added to both of these flasks and sonicated for 10 minutes. Flasks were made up with diluents and labeled as Standard stock solution 1 and 2. (3000 $\mu$ g/ml of Netupitant and 5 $\mu$ g/ml of Palonosetron)



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### Data collection and Analysis:

Optimized method: Chromatographic conditions: Mobile phase: 55%0.1% OP A buffer:  
450% Acetonitrile Flow rate : 1ml/min  
Column: DiscoveryC18 (4.6x250mm, 5µm) Detector wave length : 240nm  
Column temperature: 30°C Injection volume: 10µL Runtime:  
6min Diluents: Water and Acetonitrile in the ratio 50:50

### Methodology:

Based up on the solubility of the drugs, diluents was selected, Acetonitrile and Water taken in the ratio of 50:50

#### Preparation of Standard stock solutions

Accurately weighed 150 mg of Netupitant, 0.25mg of Palonosetron and transferred to individual 50 ml volumetric flasks separately. 3/4 th of diluents was added to both of these flasks and sonicated for 10 minutes. Flasks were made up with diluents and labeled as Standard stock solution 1 and 2. (3000µg/ml of Netupitant and 5µg/ml of Palonosetron)

#### Preparation of Standard working solutions (100% solution)

1ml from each stock solution was pipette out and taken into a 10ml volumetric flask and made up with diluents (300µg/ml Netupitant of and 0.5µg/ml of Palonosetron)

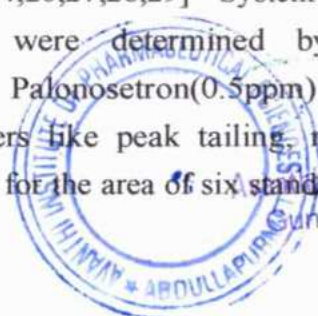
#### Preparation of Sample stock solutions

5 capsules were weighed and the average weight of each capsule was calculated, then the weight equivalent to 1 capsule was transferred into a 100ml volumetric Flask, 5ml of diluents was added and sonicated for 25 min, further the volume was made up with diluents and filtered by HPLC filters (3000µg/ml of Netupitant and 5µg/ml of Palonosetron)

#### Preparation of buffer

0.1%OPABuffer: 1ml of ConcOrthoPhosphoricacid was diluted to 1000ml with water.

Method Validation[23,24,26,27,28,29] System suitability parameters The system suitability parameters were determined by preparing standard solutions of Netupitant(300ppm)and Palonosetron(0.5ppm) and the solutions were injected six times and the parameters like peak tailing, resolution and USP plate count were determined. The % RSD for the area of six standard injections results should not be more than 2%.



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Ranga Reddy Dist.





### Specificity

Checking of the interference in the optimized method. We should not find interfering peaks in blank and placebo at retention times of these drugs in this method. So this method was said to be specific.

### Resources and budget allocation:

It will provide an overview of the resources allocated to the project, including human resources, consumables, techniques, laboratory facilities, contingencies and other project expenses. A detailed budget estimate will be presented considering the costs associated with development of new drug molecules

### Documentation and record keeping:

The outline and the documentation practices employed throughout the project. Proper documentation will facilitate traceability and aid future reference.

### Conclusion:

A simple, Accurate, precise method was developed for the simultaneous estimation of the Netupitant and Palonosetron in pharmaceutical dosage form. Retention time of Netupitant and Palonosetron were found to be 2.308min and 3.093min. %RSD of the Netupitant and Palonosetron were and found to be 0.9 and 0.6 respectively. %Recovery was obtained as 99.51% and 99.29% for Netupitant and Palonosetron respectively. LOD, LOD values obtained from regression equations of Netupitant and Palonosetron were 1.84, 0.01 and 5.59, 0.03 respectively. Regression equation of Netupitant is  $y = 7232.8x + 3439.3$  and of Palonosetron is  $y = 28857x + 97.732$ . Retention times were decreased and run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

PROJECT INVESTIGATOR



PRINCIPAL  
Avanathi Institute of Pharmaceutical Sciences  
Gunthapally (V), Hayath Nagar (M),  
Ranga Reddy Dist.





UTILIZATION CERTIFICATE

Academic Year: 2022-23

Certified that the grant of Rs. 1, 00,000 received to Avanthi Institute of Pharmaceutical sciences under the funding agency, for the Research Project entitled " Development of New Analytical Method And Validation of Anti-Neoplastic Agents Netupitant and Palonosetron In Pure And Pharmaceutical Formulation by Rp-Hplc" has been fully utilized for the purpose for which it was sanctioned and in accordance with in terms and conditions laid down in R&D policy of the institute. I have successfully published the paper *International Journal of Pharmacognosy Chemistry* 2(2), 2021, volume: 50-59

Sign of the Project Investigator  
Department: Pharmacy



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Ranga Reddy Dist.

केन्द्रीय बैंक



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RANGAREDDI CITY- RANGA REDDY  
NEAR RAMOJI FILM CITY  
RANGAREDDY  
TELANGANA-INDIA  
501512

Customer ID :879983002  
IFSC Code :UTIB0002738  
MICR Code :500211055  
Nominee Registered : N

Registered Mobile No :XXXXXXX5659  
Registered Email ID:  
Scheme :SB-TRUST/SOCIETY/NGO/GOVT

PAN :AAATA3530B

**Statement of Axis Account No :918010020435948 for the period (From : 16-02-2023 To : 17-02-2023)**

Tran Date	Chq No	Particulars	Debit	Credit	Balance	Init. Br
		<b>OPENING BALANCE</b>			<b>4725309.13</b>	
16-02-2023		IFT/011602234647/1	4000000.00		725309.13	2738
16-02-2023		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 15.02.		2500.00	727809.13	274
17-02-2023		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 16.02.		20000.00	747809.13	274
17-02-2023		TRF/INCEPTION SOURCE PRIVATE LIMITED/		400000.00	1147809.13	1456
17-02-2023		TRF/DESATLA SHEKAR/CLINOXY SOLUTIONS PVT/LTD/		100000.00	1247809.13	4267
		<b>TRANSACTION TOTAL</b>	<b>4000000.00</b>	<b>522500.00</b>		
		<b>CLOSING BALANCE</b>			<b>1247809.13</b>	

Unless the constituent notifies the bank immediately of any discrepancy found by him/her in this statement of Account, it will be taken that he/she has found the account correct.

The closing balance as shown/displayed includes not only the credit balance and / or overdraft limit, but also funds which are under clearing. It excludes the amount marked as lien, if any. Hence the closing balance displayed may not be the effective available balance. For any further clarifications, please contact the Branch.

We would like to reiterate that, as a policy, Axis Bank does not ask you to part with/disclose/revalidate of your iConnect passord,login id and debit card number through emails OR phone call Further,we would like to reiterate that Axis Bank shall not be liable for any losses arising from you sharing/disclosing of your login id, password and debit card number to anyone. Please co-operate by forwarding all such suspicious/spam emails, if received by you, to customer.service@axisbank.com

With effect from 1st August 2016, the replacement charges for Debit card and ATM card applicable on Current accounts have been revised. To know more about the applicable charges,please visit www.axisbank.com

Deposit Insurance and Credit Guarantee Corporation (DICGC) insurance cover is applicable in all Banks' deposits, such as savings, current, fixed, recurring etc\* up to maximum amount of Rs 5 Lakh including principal & interest both\* (\* or exceptions and details please refer www.dicgc.org.in )

In compliance with regulatory guidelines, the non-CTS cheque books attached to the accounts would be destroyed in banks core banking System. Thus, Non CTS cheques will not be valid for CASH, Clearing and Transfer transactions

REGISTERED OFFICE - AXIS BANK LTD,TRISHUL,Opp. Samartheswar Temple, Near Law Garden, Ellisbridge, Ahmedabad . 380006.This is a system generated output and requires no signature.

BRANCH ADDRESS - AXIS BANK LTD, VANASTHALIPURAM HYD TG, DOOR NO 5-5-1189, SY NO.15(P), PLOT NO 2/A & 3/B, SAHEB NAGAR, KURD,HAYATHNAGAR(M), LB NAGAR CIRCLE III, 500070, HYDERABAD, TELANGANA, INDIA, TEL:040-24113411 FAX:

**Legends :**

- ICONN - Transaction trough Internet Banking
- VMT-ICON - Visa Money Transfer through Internet Banking
- AUTOSWEEP - Transfer to linked fixed deposit
- REV SWEEP - Interest on Linked fixed Deposit
- SWEEP TRF - Transfer from Linked Fixed Deposit / Account
- VMT - Visa Money Transfer through ATM
- CWDR - Cash Withdrawal through ATM
- PUR - POS purchase