



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 2020-2021.

S.NO	NAME OF THE PROJECT INVESTIGATOR/Chief Investigator	NAME OF THE FUNDING AGENCY	FUND PROVIDED(INR IN LAKHS)	DEPARTMENT OF PROJECT INVESTIGATOR	DURATION OF THE PROJECT	SANCTION ORDER PAGE.NO
1	Dr. JITENDRA PATEL Dr. K. Balaji Dr. Nihar Ranjan Das	CLINOXY SOLUTIONS	2.00	PHARMACY	6 Months	7




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



CLINOXY SOLUTIONS PRIVATE LIMITED

CIN (U74910TG2021PTC155213)

Date: 22/01/2021
Hyderabad

To
The Principal
Avanathi 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 “A Novel Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Emtricitabine And Tenofovir Alafenamide In Active Pharmaceutical Ingredients And Combined Tablet Dosage Forms” 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
info@clinoxy.com

Address: KPHB 9th Phase, Hyderabad
Telangana. 500085
website: 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: 26/01/2021

Hyderabad

To
The Manager
Clinoxy Solutions Pvt Ltd,

From
The principal,
Avanathi 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

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

Copy to:

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



Date: 26/01/2021

From
The Principal
Avanathi 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 "A Novel Rp-Hplc Method Development and Validation for Simultaneous Estimation of Emtricitabine and Tenofovir Alafenamide in Active Pharmaceutical Ingredients and Combined Tablet Dosage Forms" 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 following faculty members for the project development. The list of the faculty members is listed as below:

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


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

Thanking you,

Copy to:

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3. File

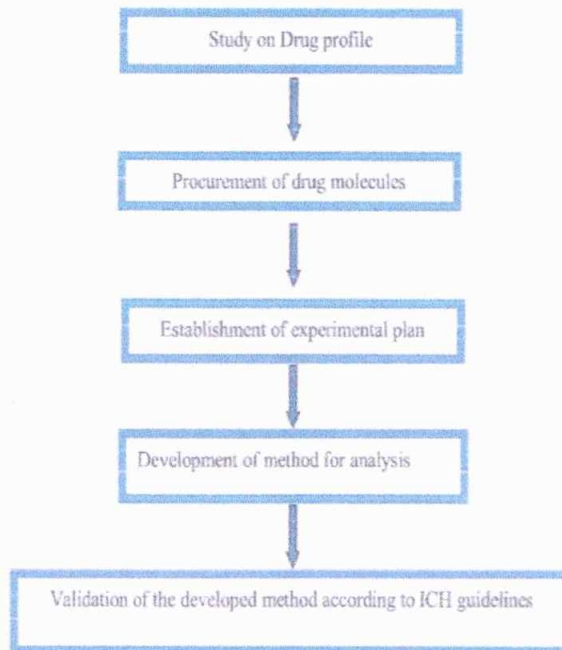



Principal

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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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Financial requirement (all figure must be INR)

S. No	Item Head	Total (in Lakh)
Capital Component		
1	Permanent Equipment (Located in lab/implementing organization) as per billing	1,00,000
2	demonstration chemicals (located at beneficiary location)	60,000/-
A	Subtotal (Capital Items)	1,60,000/-
General Component		
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	Total cost of the project (A+B)	2,00,000/-

- I. Project Cost: 2,00,000/-
- II. Contribution of consortium (if any):
- III. Total Budget (I+II): 2,00,000/-



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Gunthapally (V), Hayath Nagar (M),
Ranga Reddy Dist.



CLINOXY SOLUTIONS PRIVATE LIMITED

CIN (U74910TG2021PTC155213)

WORK ORDER

Date: 30/01/2021

WO NO: WO/CSPL/2020-21/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	2	20,000
3	Equipments & Glassware	1	1,00,000
4	Compounds Characterization	2	20,000
5	Pharmacological evaluation	1	40,000
6	Total Cost in rupees	2,00,000/-	

Rupees in words: Two lakhs Rupees only

Work Oder Valid: One Year (From 30/01/2021 to 29/01/2022)

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
info@clinoxy.com

Address: KPHB 9th Phase, Hyderabad
Telangana. 500085
website: www.clinoxy.com



Date: 31/01/2021

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

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

Respected sir,

Sub: A Novel Rp-Hplc Method Development and Validation for Simultaneous Estimation of Emtricitabine and Tenofovir Alafenamide in Active Pharmaceutical Ingredients and Combined Tablet Dosage Forms

It gives us great pleasure to let you know that the project proposal for "A Novel Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Emtricitabine And Tenofovir Alafenamide In Active Pharmaceutical Ingredients And Combined Tablet Dosage Forms" 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), Havath 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: 30/07/2021
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:

Emtricitabine (EMT) is a nucleoside reverse transcriptase inhibitor (NRTI) for the treatment of HIV infection in adults which works by inhibiting reverse transcriptase, the enzyme that copies HIV RNA into new viral DNA, resulting in early chain termination. Its chemical name is 5- fluoro-1-[(2R, 5S)-2-(hydroxymethyl)-1, 3- oxathiolan-5-yl] cytosine and the molecular formula is C₈H₁₀FN₃O₃S. Tenofovir ala fen amide (TAF) is a NRTI and a novel ester pro drug of the antiretroviral tenofovir. Its chemical name is ({[(2R)-1-(6-amino 9H-purin-9-yl) propan-2-yl] oxy} methyl) phosphoric acid and the molecular formula is C₂₁H₂₉N₆O₅.

Scope of the Project:

A stability indicating RP-HPLC method was developed and validated for the estimation of Emtricitabine (EMT), Rilpivirine (RIL), and Tenofovir (TAF) in combined dosage forms and its API. Chromatographic separation of these drugs was performed on INERTSIL column, C18 (150x4.6 ID) 5µm 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.

Project planning and scheduling:

PREPARATION OF SOLUTIONS

Mobile Phase

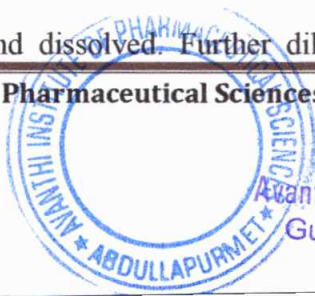
0.68% Potassium dihydrogen orthophosphate buffer solution was prepared by taking 6.8 grams of potassium dihydrogen orthophosphate in 1000 mL volumetric flask and dissolved in water, made up to the mark by adjusting the pH of the solution equal to pH = 6 with 0.1 N Noah solution. Resulting solution was filtered through 4.5µ filter under vacuum filtration. Mixture of buffer and acetonitrile in the ratio 40:60 v/v was taken, degassed in ultra sonic water bath for five minutes at room temperature and then filtered through 4.5 µ filter under vacuum filtration.

Standard and sample preparation

Weigh accurately 13 mg of EMT, 1.62 mg of RIL, and 20 mg of TAF in 100 ml of volumetric flask and dissolve in 10 ml of Mobile Phase and make up the volume with Mobile Phase. From that, 13 µg/ml of EMT, 1.62 µg/ml of RIL, and 20 µg/ml of TAF were prepared by diluting 5.3 ml–10 ml with Mobile Phase which was used as stock solution.

5 tablets were weighed and taken into a mortar and crushed to fine powder and uniformly

mixed. Weight equivalent to 34.62 mg and dissolved. Further dilutions were prepared in five





replicates of 13 µg/ml of EMT, 1.62 µg/ml of RIL, and 20 µg/ml of TAF which were made by adding 5.3 ml of stock solution to 10 ml of Mobile Phase which was used as sample solution.

Data collection and Analysis:

Forced degradation studies of the fixed dose combination of the drug were carried out by treating the sample under stress conditions like acid and base hydrolysis, oxidation, photolytic and thermal degradation, and resultant degradation products was investigated. These study help to know the stability characteristics of the drug and the possible degradation products.

Preparation of Solution for Degradation Studies: Weight equivalent to 1 tablet, i.e., 200 mg of EMT, 25 mg of RIL, and 25 mg of TAF into 50 ml capacity standard volumetric flask. The contents in the flask were dissolved using methanol and sonicate it and diluted up to the mark with methanol.

Preliminary Study: In the preliminary examination, observations were made about sample stability, including exposure of solid state samples to heat and light and exposure of solutions to various pH and oxidative conditions. The preliminary study can also be used to aid in the development of an analytical method.

Acid Degradation Condition: Pipette 2 ml of the above solution into a 10ml volumetric flask and 3 ml of 0.1N HCl was added. Then, the volumetric flask was kept at 60 °C for 6 h and then neutralized with 0.1N NaOH and make up to 10 ml with diluents. Filter the solution with 0.22 microns syringe filters and placed in vials. Using mobile phase finally the volume was made up to the mark, and the percentage of degradation was calculated

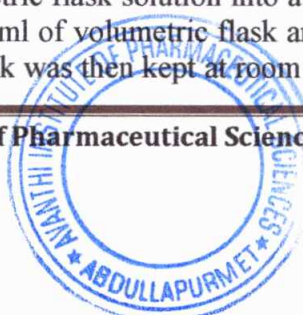
Methodology

Alkali Degradation Condition: Pipette 2 ml of the above solution into a 10 ml volumetric flask into a 10ml volumetric flask and add 3 ml of 0.1N NaOH was added in 10 ml of volumetric flask. Then, the volumetric flask was kept at 60 °C for 6 h and then neutralized with 0.1N HCl and make up to 10 ml with Diluents. Filter the solution with 0.22 microns syringe filters and placed in vials. Finally, volume was made up to the mark with the mobile phase, and the percentage of degradation was calculated.

Thermal Induced Degradation Condition: Rilpivirine, Emtricitabine, and Tenofovir alafenamide named sample was taken in Petridish and kept in a hot air oven at 110 °C for 24 h. Then the sample was taken and diluted with diluents and injected into HPLC and percentage of degradation was calculated.

Photolytic Degradation Condition: A 5 ml a liquid of the above stock solution was exposed to sunlight for about 6 h, and then the sample diluted with 5 ml of mobile phase and the percentage of degradation was calculated. **Oxidative Degradation Condition:** Pipette 2 ml

above stock solution 2 into a 10 ml volumetric flask solution into a 10ml volumetric flask 1 ml of 3% w/v of hydrogen peroxide added in 10 ml of volumetric flask and the volume was made up to the mark with diluents. The volumetric flask was then kept at room temperature for 15 min. Filter the





solution with 0.45 microns syringe filters and place in vials and percentage of degradation was calculated.

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 from plant species

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



UTILIZATION CERTIFICATE

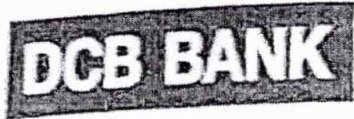
Academic Year: 2020-21

Certified that the grant of Rs. 2,00,000 received to Avanathi Institute of Pharmaceutical sciences under the funding agency, for the Research Project entitled " **A Novel Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Emtricitabine And Tenofovir Alafenamide In Active Pharmaceutical Ingredients And Combined Tablet Dosage Forms**" 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 **Volume3, issue6 June2021,pp: 2513-2521 www.ijaem.net ISSN:2395-5252**

Sign of the Project Investigator
Department: Pharmacy



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Avanathi's Institute of Pharmaceutical Sciences
Gunthapally (V), Erivath Nagar (M),
Rangareddy Dist.



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Date

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⑈ 144300⑈ 500072006⑈ 094718⑈. 29

2020 - 2021

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 :XXXXXXX5659

Registered Email ID:

PAN :AAATA3530B

Scheme :SB-TRUST/SOCIETY/NGO/GOVT

Statement of Axis Account No :918010020435948 for the period (From : 20-08-2021 To : 21-08-2021)

Tran Date	Chq No	Particulars	Debit	Credit	Balance	Init. Br
		OPENING BALANCE			131346.13	
21-08-2021		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 19.08		176060.00	307406.13	274
21-08-2021		TRF/G SURESH/JRS LABS/		85000.00	392406.13	1043
21-08-2021		TRF/CLINOXY SOLUTIONS PVT LTD/		200000.00	592406.13	58
		TRANSACTION TOTAL	.00	461060.00		
		CLOSING BALANCE			592406.13	

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/diseosing 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
TIP/ SCG	-	Surcharge on usage of debit card at pumps/railway ticket purchase or hotel tips
RATE.DIFF	-	Difference in rates on usage of card internationally
CLG	-	Cheque Clearing Transaction