



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 2021-2022.

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	Grants received	
						Cheque page no	Statement page no
1	Dr. M.RAMAKRISHNA Dr. K.Balaji Dr. Nihar Ranjan Das	SS PHARMA SOLUTIONS	4.15	PHARMACY	6 MONTHS	14	15
2	Dr.Nagaraju kandukoori Dr. K.Balaji Dr. Nihar RanjanDas	JRS LABS	0.85	PHARMACY	6 MONTHS	29	30




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



SS Pharma Solutions
We connect your goal

Date: 21/06/2021
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

SS PHARMA LABS were looking for a team of qualified faculty members at your college in Pharmacy Department who can work on "Formulation and Evaluation of Effervescent Floating Tablets of Acyclovir" 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.

For
SS PHARMA SOLUTIONS

V. Srinivas
Director

Authorized Signatory



Managing Director



**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: 24/06/2021

Hyderabad

To
The Manager,
SS Pharma 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

Principal
Avanthi'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: 24/06/2021

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

To
The Managing Director,
Ss Pharma 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 "Formulation and Evaluation of Effervescent Floating Tablets of Acyclovir" 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 faculty members for project development. The following is the list of faculty members

1. Dr.M.RAMA KRISHNA (Project Investigator)
2. Dr. K.Balaji (Chief Investigator)
3. Dr. Nihar Ranjan Das (Technical Advisor)

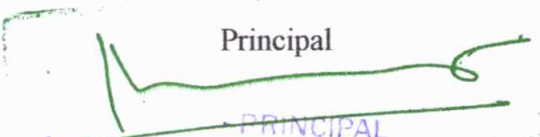
Please be assured that we will make every effort to complete the project as quickly as we can.

Thanking you,

Copy to:

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Principal

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

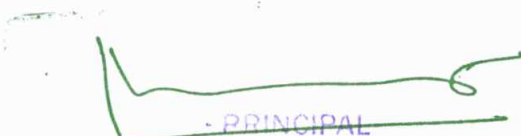


Financial requirement (all figure must be INR)

S. No	Item Head	Total (in Lakh)
Capital Component		
1	Permanent Equipment (Located in lab/implementing organization) as per billing	3,00,000
2	demonstration chemicals (located at beneficiary location)	65,000/-
A	Subtotal (Capital Items)	3,65,000/-
General Component		
1	Manpower and Contingencies	20,000/-
2	Non Consumables	20,000/-
3	Travel	5,000/-
4	Overhead	-----
5	PC	-----
6	Printer and Scanner	5,000/-
B	Subtotal (General)	50,000/-
C	Total cost of the project (A+B)	4,15,000/-

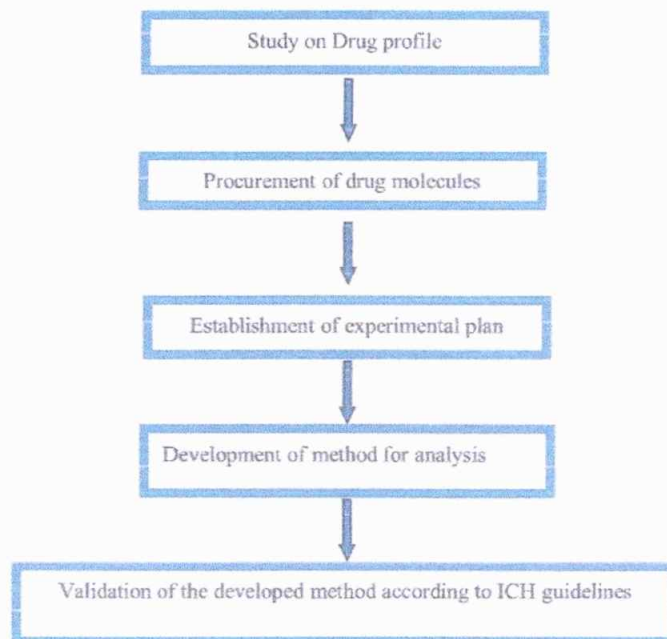
- I. Project Cost: 4,15,000/-
- II. Contribution of consortium (if any):
- III. Total Budget (I+II): 4,15,000/-




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



FLOWCHART OF PROJECT PROCEDURE:

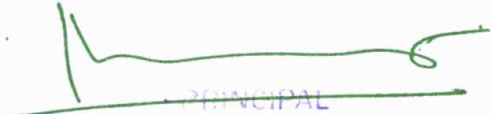


The study deals with the new stability indicating method development and validation for the simultaneous determination of Diacerein, Glucosamine sulphate and Methyl sulfonyl methane by RP-HPLC.

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



SS Pharma Solutions
We connect your goal

WORK ORDER

Date: 28/06/2021

WO NO: WO/SSP/2021-22/CO1

HYDERABAD

To
The Principal
Avanathi 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	25,000
2	Chemicals ,Reagents & Solvents	3	20,000
3	Equipments & Glassware	2	3,00,000
4	Compounds Characterization	2	20,000
5	Pharmacological evaluation	1	50,000
6	Total Cost in rupees		4,15,000/-

Rupees in words: Four lakhs fifteen thousand Rupees only

Work Oder Valid: One Year (FROM 28/06/2021 TO 27/06/2022)

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
SS PHARMA SOLUTIONS

V. Srinivas
Director

Authorized Signatory



+918790142727 | info@sspharmasolutions.com | www.sspharmasolutions.com
Plot No:8, 2nd floor, Beside ALEAP maingate, Pragathi nagar, Hyderabad, Telangana, India-500090



Date: 30/06/2021

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

To
The Managing Director,
Ss Pharma Solutions,
Hyderabad,

Respected sir,

Sub: Formulation and Evaluation of Effervescent Floating Tablets of Acyclovir

It gives us great pleasure to let you know that the project proposal for "Formulation and Evaluation of Effervescent Floating Tablets of Acyclovir" 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,

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PRINCIPAL

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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: 28/01/2022
Hyderabad

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

To
Proprietor,
Ss Pharma Solutions,
Hyderabad,

Respected Sir,

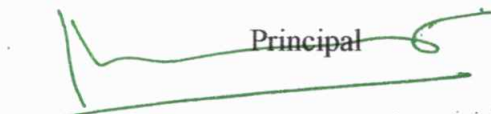
Sub: Project Completion-reg.

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



PROJECT REPORT:

Introduction:

Acyclovir is the prototype antiviral agent used to treat various types of herpes infections. Since, Acyclovir [1,2] was the first antiviral to be considered the gold standard for the treatment of herpes infections, all other anti-herpes virus medications are compared to it. Acyclovir was seen as the start of a new era in antiviral therapy, as it is extremely selective and low in cytotoxicity.

Scope of the Project:

As traditional medicine can complement conventional medical practices by providing additional treatment options. Integrating traditional medicine with modern healthcare systems allows for a comprehensive approach that combines the strengths of both systems. This integration can enhance patient care, improve treatment outcomes, and provide a more comprehensive range of therapeutic use. The scope of the project includes that to develop new molecules from plant species and chemical examination of metabolites from selected plants.

Project planning and scheduling:

Materials:

Acyclovir was obtained as a gift sample from Macleod's Pharmaceuticals, Mumbai, India. HPMC K100M, Sodium PVP K30, sodium Bicarbonate and microcrystalline cellulose, Xanthan-Gum and Guar-gum were received from S D fine Chemicals, Mumbai. Talc, magnesium stearate and lactose were of laboratory grade.

Methods:

Preparation of effervescent floating matrix tablets: Effervescent floating matrix tablets containing Acyclovir are prepared by direct compression technique using variable concentrations of HPMCK100M, Sodium Bicarbonate, PVPK30, Xanthan-Gum, Guar-gum and Cellulose microcrystalline cellulose. The powder mixture containing drug, polymer, magnesium stearate and talc. All the ingredients are accurately weighed and passed through sieve no.40 and blended thoroughly in a mortar. Quantities of 600 mg of the mixture are weighed and were directly compressed using Lab Press multi station rotary punching machine.

EVALUATION OF FLOATING MATRIX TABLETS:

Pre compression parameters:

Color and appearance, Assay of Acyclovir (as per BP), Melting point determination, Solubility, U V spectra, IR spectra, Differential scanning calorimetric, Angle of repose, bulk density, tapped density, Carr's (compressibility) index, Hausner's ratio and drug content are determined. To study out the flow property of granules during formulation. The details are given in the following table.



Data collection and Analysis:

Evaluation of blend:

Angle of Repose, Carr's Compressibility Index, Bulk Density and Tapped Density, Hausner's ratio, Differential scanning calorimetric (DSC) studies of drug with polymer, FTIR studies of drug with polymer for incompatibilities.

Post compression parameters [19] General appearance:

The formulated tablets are evaluated for general appearance. Viz., color, odor, shape

Tablet Dimension:

The thickness and diameter of the tablets are carried out using digital vernier caliper. Three tablets are used from each batch and results were expressed in millimeter (mm).

Weight variation test:

Twenty tablets are selected at random, individually weighed in a single pan electronic balance and the average weight is calculated. The uniformity of weight is determined according to I.P. specification. As per IP (2007) not more than two of individual weights should deviate from average weight by more than 5% and none deviate more than twice that percentage.


Hardness test:

Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shocks of handling in manufacture, packing and shipping. Monsanto hardness tester is used to measure the hardness of tablet. Three tablets from each batch are used for hardness test and results are expressed in Kg/cm²

Methodology:

Acid buffer pH 1.2 (900 ml) is filled in dissolution apparatus and temperature of the medium is set at 37°C ± 0.5°C. One tablet of different batch is placed in each dissolution vessel and the rotational speed of paddle was set at 50rpm. 5 ml of sample is withdrawn at predetermined time interval of every one hour for up to 12 hours and same volume of fresh medium is replaced immediately. The withdrawn sample is diluted to 25ml in volumetric flask and filtered through 0.45µ membrane filter. The resultant samples are analyzed for drug content at 256.2 nm using UV-Visible spectrophotometer




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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 molecules from 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:

For the formulation of floating tablets HPMC K15M, and PVP K30 was used as matrix forming agent and floating enhancer. Other excipients used are sodium bicarbonate (gas generating agent), MCC, talc and Magnesium stearate (lubricating agent). Fourier transform Infrared spectroscopy confirmed the absence of any drug/polymers/excipients interactions. One of the simplest means of improving the bioavailability of an active substance is to improve its dissolution by adding olubilizing agents, such as povidone. It forms water- soluble complexes with many active. With some such substances, it may be sufficient to produce a physical mixture. The tablets were directly compressed using Lab Press multi station rotary punching machine The prepared floating tablets were evaluated for hardness, Weight variation, formulation showed good floating property and a controlled drug release. Stability studies were carried out for F7 formulation, they had showed good stability when stored at accelerated stability state as per the ICH guideline and the values were within permissible limits. It was observed that Formulations F7 showed good drug release up to 12 hrs with minimum FLT. All formulations were subjected for four different models viz. Zero order, First order, Higuchi matrix and Peppas model equations and F1 to F9 formulation best fit in into the Peppas model .It was revealed that polymers and sodium bicarbonate ratios had significant influence on drug release. Thus conclusion can be made that stable floating dosage form can be developed for acyclovir for the controlled release by floating tablets

M.R. Kundu

PROJECT INVESTIGATOR



PRINCIPAL

- PRINCIPAL

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



UTILIZATION CERTIFICATE

Academic Year: 2021-22

Certified that the grant of Rs. 4, 15,000 received to **Avanathi Institute of Pharmaceutical sciences** under the funding agency, for the Research Project entitled "**Formulation and Evaluation of Effervescent Floating Tablets of Acyclovir**" 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 December2020, ||JournalDOI:10.36713, SJIF Impact Factor: 7.032,



MR. Kiran

Sign of the Project Investigator
Department Pharmacy

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



भारतीय स्टेट बैंक
State Bank Of India

(16783) NRI KUKATPALLY
MIG 1 166
ROAD 140 1, KPMB COLONY, KUKATPALLY
HYDRABAD 500077
Tel : 9140 23151033 Fax : IFS Code : SBIN0016783 SWIFT :

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PAY Avanti Institute of Pharmaceutical Sciences

को या उनके आदेश पर OR ORDER

रुपये RUPEES Four Lakhs Fifteen Thousand

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415000

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VALID UP TO ₹ 50 LACS AT NON HOME BRANCH FOR NON CASH TRANSACTION ONLY

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2021 - 2022

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:

PAN :AAATA3530B

Scheme :SB-TRUST/SOCIETY/NGO/GOVT

Statement of Axis Account No :918010020435948 for the period (From : 14-02-2022 To : 15-02-2022)

Tran Date	Chq No	Particulars	Debit	Credit	Balance	Init. Br
		OPENING BALANCE			4384884.13	
14-02-2022		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 11.02		139520.00	4524404.13	274
15-02-2022		AVANTHI INST OF PHARMACEUTICAL SCIENCE - 08 14.02.		854060.00	5378464.13	274
15-02-2022		TRF/SS PHARMA SOLUTIONS/		415000.00	5793464.13	6783
		TRANSACTION TOTAL	.00	1408580.00		
		CLOSING BALANCE			5793464.13	

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



JRS Labs

An ISO 9001:2015 Certified Analytical Laboratory

Date: 21/06/2021

HYDERABAD

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

Date:

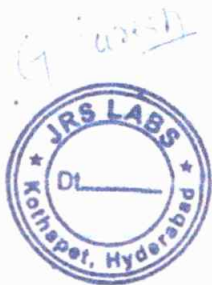
Dear Sir,

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

JRS Labs are offering the ideal platform, for promoting and supporting research and development in the area of Pharmacy and Promoting innovation. In particular, we offer result oriented framework that corresponds with the needs of Industry. 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 "Formulation and in vitro evaluation of trifluoperazine HCL Gastro retentive Floating Tablets" 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



D.No. 11-8-22, Mig-26,
Third Floor, Kothapet, Huda Colony,
Near Victoria Memorial School.



**AVANTHI INSTITUTE OF
PHARMACEUTICAL SCIENCES**

(Approved by PCI, AICTE & Affiliated to JNTUH)

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



Date: 24/06/2021

Hyderabad

To
The Manager
Jrs Labs

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.

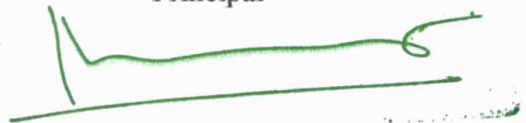
We are ready to submit a detailed project proposal with all necessary details upon confirmation from your end.

Thank you once again.

Yours Sincerely

Principal




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

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Date: 24/06/2021

From
The Principal
Avanathi Institute of Pharmaceutical sciences,
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To
The Managing Director,
Jrs Labs,
Hyderabad,

Respected sir,

Sub: Project Development-Acceptance reg

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- 1 Dr.Nagaraju kandukoori (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,



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Principal

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Financial requirement (all figure must be INR)

S. No	Item Head	Total (in Lakh)
Capital Component		
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2	Non Consumables	5,000/-
3	Travel	5,000/-
4	Overhead	-----
5	PC	-----
6	Printer and Scanner	5,000/-
B	Subtotal (General)	20,000/-
C	Total cost of the project (A+B)	85,000/-

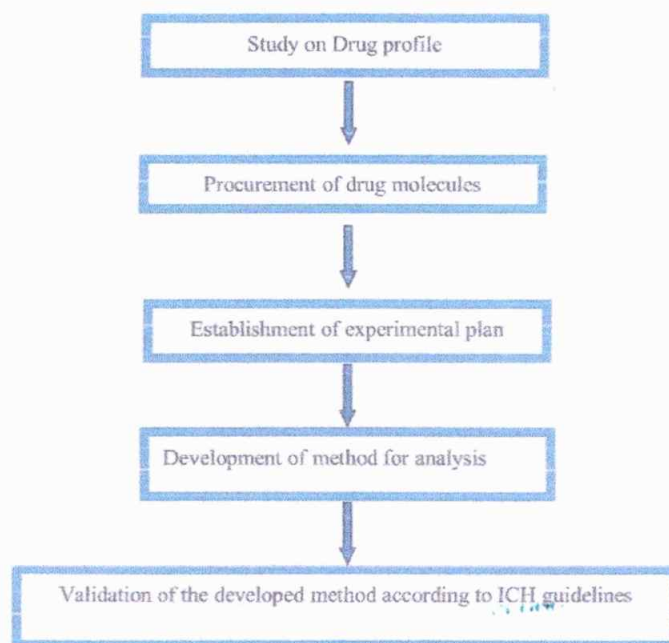
- I. Project Cost: 85,000/-
- II. Contribution of consortium (if any):
- III. Total Budget (I+II): 85,000/-



PRINCIPAL
Avanathi's 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 Diacerein, Glucosamine sulphate and Methyl sulfonyl methane by RP-HPLC.

Objectives:

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

Date:

Date: 28/06/2021

HYDERABAD

WORK ORDER

WO NO: WO/JRS/2021-22/CO2

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

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

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S.NO	Description	Quantity in no	Unit Cost Rs.
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2	Chemicals ,Reagents & Solvents	1	5,000
3	Equipments & Glassware	1	55,000
4	Pharmacological evaluation	1	20,000
5	Total Cost in rupees		85,000/-

Rupees in words: Eighty five thousand Rupees only

Work Oder Valid: One Year (FROM 05/02/2021 TO 04/02/2022)

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 JRS LABS

D.No. 11-8-22, Mig-26,
Third Floor, Kothapet, Huda Colony,
Near Victoria Memorial School.



Date: 30/06/2021

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

To Managing Director,
Jrs Labs,
Hyderabad,

Respected sir,

Sub: Formulation and in vitro evaluation of trifluoperazine HCL Gastro retentive Floating Tablets

It gives us great pleasure to let you know that the project proposal for "Formulation and in vitro evaluation of trifluoperazine HCL Gastro retentive Floating Tablets" 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,



PRINCIPAL

Copy to:

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

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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: 28/01/2022

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

To
Proprietor,
Jrs Labs,
Hyderabad.

Respected Sir,

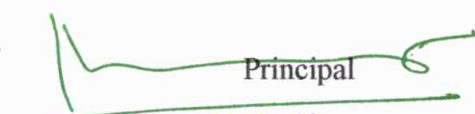
Sub: Project Completion-reg.

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:

Development of oral controlled release systems has been a challenge to formulation scientists because of the difficulty in localizing the system in target areas of the gastrointestinal tract. In recent years, per oral dosage forms for gastric retention have attracted more and more attention for their theoretical advantage in gaining control over the time and the site of drug release. This would be particularly valuable for drugs that exhibit an absorption window in the upper part of the small intestine. Gastric retention has received significant interest in the past few decades as most of the conventional oral delivery systems have shown some limitations related to fast gastric emptying time. A gastro retentive dosage form (GRDF) can overcome this problem and is particularly useful for drugs that are primarily absorbed in the duodenum and upper jejunum segments.

Scope of the Project:

The purpose of this study is to prepare a bilayer gastro retentive tablet of Trifluoperazine hydrochloride using direct compression technology and optimize the type and concentration of polymer to give maximum retentive effect with good drug release profile. Trifluoperazine hydrochloride having biological half-life (7-8hr) was selected model drug as it is neuroleptic, antiemetic agent used to treat schizophrenia, anxiety disorder & other psychoses having first pass metabolism, low oral bioavailability, maximum absorption in the upper part of GIT hence it is suitable for gastro retentive system. In this study, a bilayer tablet was prepared which contains an immediate release portion and a floating layer. Immediate release of drug controlled by super disintegrant sodium starch glycolate. Starch microcrystalline cellulose were used as diluents. For Sustain Release Layer various hydrophilic & hydrophobic polymers such as HPMC K100M, CP934 & EUDRAGIT RS100 were used. Sodium bicarbonate, and citric acid as gas generating agent, DCP as additive combine with the polymer to form the floating layer. The optimum concentration of sodium bicarbonate was found to be 14% for floating buoyancy. The bilayer tablets were characterized by lag time, floating time, weight variation, drug content and dissolution profile. It is concluded on the basis of buoyancy and in-vitro release kinetics that optimized formulation FL-7 containing diluents to total polymer ratio 1:3 & HPMC K100M to CP 934 ratio 3:0.5 gave the best in-vitro release of 97.33% in 12 hrs was carried out in 1.2 pH.



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Project planning and scheduling:

The flow properties of granules were evaluated in terms of angle of repose, Carrindex and Hausner's ratio. The angle of repose of immediate release and sustain release layer was determined by fixed funnel method. For determination of angle of repose (θ) the granules were poured through the walls of a funnel, which was set at a place such that its lower tip was at a height of closely 2.0 cm above from ground surface. The granules were poured up to the time when upper tip of the pile surface touched the lower tip of the funnel. The \tan^{-1} of (height of the pile/ radius of its base) give the angle of repose. Granules were poured gently through a glass funnel into a graduated cylinder cut exactly to 10 ml mark. Excess granules were removed using a spatula and the weight of the cylinder with pellets required for filling the cylinder volume was calculated. The cylinder was then tapped from a height of 2.0cm until the time when there was no more decrease in the volume.

Hardness:-

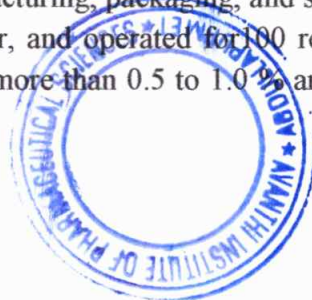
Tablet hardness has been defined as the force required breaking a tablet in a diametric compression test. A tablet was placed between two anvils of hardness tester, force was applied to the anvils, and the crushing strength that causes the tablet to break was recorded in kg/cm^2

Weight variation:-

The weight variation test is done by taking 20 tablets randomly and they were weighed accurately. The composite weight divided by 20, provides an average weight of tablet. Not more than two of the individual weight deviates from the average weight by 5 %. And none should deviate by more than twice that percentage. The average weight and standard deviation of the tablets were calculated.

Friability:-

Tablets require certain amount of strength or hardness and resistance to with stand mechanical shock of handling in manufacturing, packaging, and shipping. A pre-weighed sample (10 tablets) was placed in the friabilator, and operated for 100 revolutions, then again weighed the tablets. Percentage loss should not more than 0.5 to 1.0 % and the % friability was calculated using the formula.



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Data collection and Analysis:

Evaluation of blend:

Angle of Repose, Carr's Compressibility Index, Bulk Density and Tapped Density, Hauser's ratio, Differential scanning calorimetric (DSC) studies of drug with polymer, FTIR studies of drug with polymer for incompatibilities.

Tablet Dimension:

The thickness and diameter of the tablets are carried out using digital vernier caliper. Three tablets are used from each batch and results were expressed in millimeter (mm).

Weight variation test:

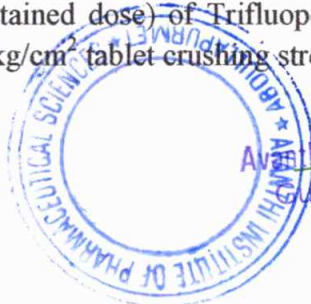
Twenty tablets are selected at random, individually weighed in a single pan electronic balance and the average weight is calculated. The uniformity of weight is determined according to I.P. specification. As per IP (2007) not more than two of individual weights should deviate from average weight by more than 5% and none deviate more than twice that percentage.

Hardness test:

Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shocks of handling in manufacture, packing and shipping. Monsanto hardness tester is used to measure the hardness of tablet. Three tablets from each batch are used for hardness test and results are expressed in Kg/cm²

Methodology

Preparation of bilayer tablet: All ingredients of each layer were weighed properly and passed through sieve No. 60. The ingredients of immediate layer and sustain layer were mixed separately in mortar and the ingredients of immediate layer lubricated with magnesium stearate (1 % w/w) and aerosol (1 % w/w). The composition no immediate release layer is kept constant for all formulations. Powder mixture of sustain layer was transferred manually into the die cavity, Slightly compressed sustain release powder and then powder mixture of immediate layer was transferred over the sustain layer, finally after addition of the immediate layer into the die cavity, the total die cavity content was compressed with 9 mm diameter concave punch tooling. Each bilayer tablet contained 6 mg (2 mg as immediate release dose and 4 mg as sustained dose) of Trifluoperazine hydrochloride. Compression was controlled to produce a 5 kg/cm² tablet crushing strength



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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:

Initially for biphasic release of drug, immediate release layer of bilayer tablet containing Trifluoperazine hydrochloride was prepared by using super disintegrant i.e., sodium starch glycolate, starch and micro crystalline cellulose as a diluents. Sustained release layer was prepared by using various hydrophilic and hydrophobic polymers such as HPMC K100M, CP 934 and Eudragit RS100. Bilayer tablets when comes in contact with gastric fluid quickly releases the immediate release layer and start onset of action, subsequently floating sustained release layer floats over gastric fluid and release the drug in sustained manner. It was concluded on the basis of buoyancy and *in-vitro* release kinetics that optimized formulation FL-7 containing diluents to total polymer ratio 1:3 and HPMC K100M to CP934 ratio 3:0.5 gave the best *in-vitro* release of 97.33% in 12 hrs was carried out in 1.2 pH (simulated gastric fluid), bilayer floating tablet showed sustained release of the drug in acidic condition (pH 1.2) and the drug release was found to be approximately linear

PROJECT INVESTIGATOR

PRINCIPAL



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



UTILIZATION CERTIFICATE

Academic Year: 2021-22

Certified that the grant of Rs. 85,000 received to **Avanthi Institute of Pharmaceutical sciences** under the funding agency, for the Research Project entitled " **Formulation and in vitro evaluation of trifluoperazine HCL Gastro retentive Floating Tablets**" 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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Ranga Reddy Dist.



C 171 MIG PHASE II, VANASTHALIPURAM,
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AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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 MICR Code :500211055
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Registered Mobile No :XXXXXX5659

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/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
- 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