3.1.1. Grants received from Government and non-governmental agencies for research projects, endowments in the institution during the years 2018-2019

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 pageno	Statement page no
1	Dr. Nihar Ranjan Das Dr. M. Rama Krishna Dr.B.Manjula	KP LABS	4.00	PHARMACY	6Months	28	29
2	Dr. Nihar Ranjan Das Dr. M. Rama Krishna Dr. B. Manjula	KP LABS	1.00	PHARMACY	6Months	28	29

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

KP LABS
QUALITY- HONESTY-RELIABILITY

Date: 25/05/2018
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

KP 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 endeavor 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 "Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms by RP-HPLC" 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

KP LABS KDPL KOTHAPET, HYDERABAD

Authorized Signature

Date: 26/05/2018
Hyderabad

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

Copy to:

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

ABDULLAPURMET * AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES *

Date: 26/05/2018

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

To
The Managing Director,
KP Labs,
Hyderabad,

Respected sir,

Sub: Project Development-Acceptance reg

It gives us great pleasure to let you know that the project proposal for "Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms 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 is pleasure to allot the following faculty members for Project Development I'm pleased to depute

1. Dr. Nihar Ranjan Das (Project Investigator)
2. Dr. M. Rama Krishna (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,

Principal

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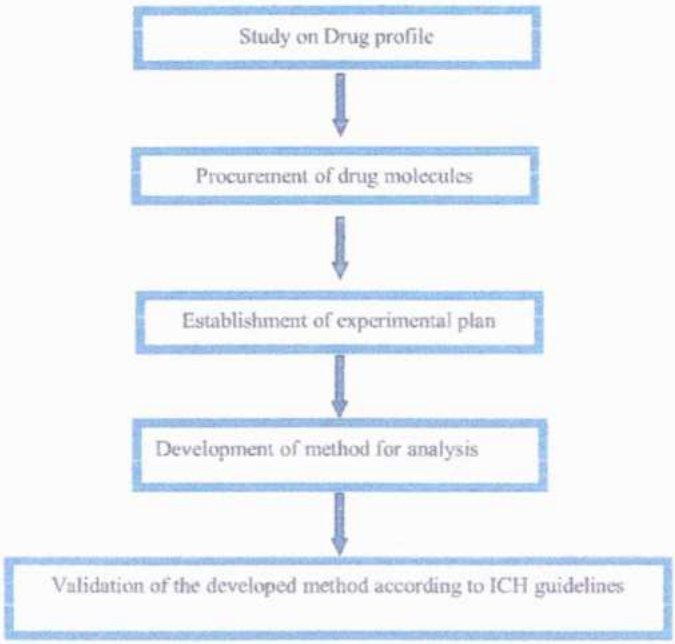
- PRINCIPAL
Avanthi's Institute of Pharmaceutical Sciences
Gunthapally (V), Hayath Nagar (M),
Ranga Reddy Dist.

FLOWCHART OF PROJECT PROCEDURE:



The study deals with the new stability indicating method development and validation for the simultaneous determination of 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.

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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)
Capital Component		
1	Permanent Equipment (Located in lab/implementing organization) as per billing	3,00,000
2	Fabricated systems/demonstration models (located at beneficiary location)	40,000/-
A	Subtotal (Capital Items)	3,40,000/-
General Component		
1	Manpower and Contingencies	20,000/-
2	Non Consumables	20,000/-
3	Travel	10,000/-
4	Overhead	--------
5	PC	---------
6	Printer and Scanner	10,000/-
B	Subtotal (General)	60,000/-
C	**Total cost of the project (A+B)**	4,00,000/-

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

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

KP LABS
QUALITY- HONESTY-RELIABILITY

WORK ORDER

Date: 01/06/2018

WO NO: WO/KP LABS/2018-19/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	10,000
2	Chemicals ,Reagents & Solvents	3	20,000
3	Equipments & Glassware	2	3,00,000
4	Compounds Characterization	4	10,000
5	Analytical method Development	1	60,000
6	Total Cost in rupees	4,00,000/-	

Rupees in words: Four lakhs rupees only

Work Oder Valid: One Year (FROM 01/06/2018 TO 31/05/2019)

KP LABS KOTHAPET HYDERABAD KDPL

Authorized Signature

Terms& Conditions:

- Preparation of detailed drawings/Lay outs based on the reference design provided by the customer.
- Taking physical design for review and approval of our customer
- Submission of designs/lay outs for review and approval of our customer
- Incorporate any comments/feed back given by customer in the design/layouts
- Preparation of designs, lay outs, algorithms, part design, bill of materials for all designs.
- Preparation of built up designs, lay outs after completion of fabrication/Installation at site.

WORKING LOCATION: You're Premises

For KP LABS

PURCHASE MANAGER

Date: 02/06/2018

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

To
The Managing Director,
KP Labs,
Hyderabad,

Respected sir,

Sub: Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms by RP-HPLC

It gives us great pleasure to let you know that the project proposal for "Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms 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,

Principal

Copy to:

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AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

Date: 01/12/2018

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

To
Proprietor,
KP 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:

Telmisartan,4-[(2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)-benzimidazole-1-yl)methyl]-biphenyl-2-carboxylicacid, is a selective angiotensin II type1receptor(AT1R) blocker, which belongs the group of angiotensin receptor antagonists. It inhibits the angiotensin in II receptor in a way that the effect of angiotensin II is blocked resulting in a decrease of blood pressure. There are different mechanisms increasing the activity of the sympathetic nervous system, causing boosted Sodium revertive resorption in the kidneys and promotion of the secretion of aldosterone in the adrenal glands. The most recent clinical trials demonstrated that telmisartan also has preventive roles against is chemic heart diseases in diabetic patients with a similar potency to angiotensin converting enzyme meinhibitor.Several studies recently suggest that the effects of telmisartan are mediated via not only blockade of AT1R but also activation of peroxisome proliferators-activated receptor (PPAR)a central regulator of insulin and glucose metabolism. It is believed that telmisartan dual mode of action may provide protective benefits against the vascular and renal damage caused by diabetes and cardio vascular diseases (CVD).Telmisartan has binding affinity3000 times with AT-2 receptorthanAT-1receptor.Telmisartanisalso having maximum half-life in sartans - 24 hrs

Scope of the Project:

HPLCmethodfortheestimationofTelmisartanusingeprosartanmesylateasaninternalstandard (IS)in bulk and tablet dosage form. Separation was achieved under optimized chromatographic conditions on a phenomenex C-18 column (250 X 4.6 mm, particle size 5µ) with mobile phase consisting of 10m Mpotassium dihydrogenphosphate buffer :methanol in the ratio 20:80v/v,PH adjusted to 5.8 with 10%v/v ortho phosphoric acid at a flow rate of 0.8ml/min at ambient temperature. The detection was carried out at 296 nm using waters UV Visible detector. The calibration curve was linear in the concentration range of 1–10mg/ ml (r2=0.9979).The limited detection and the limit of quantification were found to be50ng/ml and 80ng/ml respectively.The amount of Telmisartan present in the formulation was found to be 99.95.The method was validated statisticallyusingtheSDand%RSDandthevaluesarefoundtobewithinthelimitsandtherecovery studies were performed. The percentage recoveries were found to be99.55±0.7211 %.So, the proposedmethodwasfoundtobesimple,specific,linear,andrugged.Hence it can be applied for routine analysis of Telmisartan in bulk and Pharmaceutical formulations.

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Project planning and scheduling:

Preparation of Standard stock solutions

Stock solutions of telmisartan with a concentration of 1000µg/ml was prepared by dissolving 25mg of telmisartan into 25ml volumetric flask and add about 25ml of diluents (methanol)and sonic ate to dissolve completely, make volume up to the mark with the same diluent. The stock solution is further diluted to obtain standard solutions of 1, 3, 5, 7, 9 and 10µg/ml of telmisartan.

System suitability

The HPLC system was stabilized for forty min. One blank followed by six replicates of a single calibration standard solution of Telmisartan was injected to check the system suitability. To ascertain the systems suitability for the proposed method, a number of parameters such as theoretical plates, peak a symmetry, retention

Data collection and Analysis:

Accuracy (Recovery studies)

The accuracy of the method is determined by calculating recovery of telmisartan and IS by the method of addition. Known amount of telmisartan and IS at 1µg/ml, 5µg/ml and 10µg/ml. The recovery studies are carried out and the mean percentage recovery of telmisartan and IS a teach level is not less than 95% and not more than 105%.

Stress Analysis

Stability testing studies of Telmisartan were carried out according to ICH guidelines by subjecting it to different stress conditions. Photo stability was carried out in photo stability chamber containing 40^0C 75% RH, UV light for six hours according to ICH Guidelines.

Under acidic condition: 1ml of 5µg/ml of drug solution and internal standard (Eposartan) were subjected to 0.1N HCl for six hours. The peak area of internal standard was degraded to 50% was observed, but there was no degradation observed in drug's peak area.

In Basic Condition: 1ml of 5µg/ml of drug solution and internal standard (Eposartan) was subjectedto0.1NNaOHforsixhours.Retention time of drug gradually decreased as well as peak area of drug also decreased.

UV Exposure: No significant changes were observed in UV light.

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Oxidative Stress Analysis: when subjected to oxidative stress analysis both the drug and internal standard were also degraded to 50%.

Temperature Effect: There was no significant change, upon changing temperature of the drug and internal standard.

Methodology

Reagents and chemicals

Telmisartan (99.4%) was obtained from local manufacturer, Hyderabad, India, as if sample. Methanol (HPLC Grade), Potassium dihydrogen phosphate (AR Grade), ortho□phosphoric acid (AR Grade) was purchased from E. Merck (India) Ltd. Mili□Q water was used throughout the experiment.

Instrumentation and chromatographic conditions

The HPLC system consisted of a ShimadzuLC- 20AT liquid chromatographic pump, Rheodyne injection port(Rheodyne,Cotati,CA,USA)witha 20µl sample loop and SPD-M20A Photo diode array(PDA)detector(Shimadzu,KyotoJapan).Data collection, integration and calibration were accomplished using LC Solutions chromatography Data system.

Chromatography was performed on a SYMMETRY C18 packed column (5µm, 250×4.6mm particle size, WATERS, Ireland) maintainedat40^{0}c.TheHPLC system consists of Shimadzu LC-20 AT liquid chromatographic pump, Rheodyne injection port (Rheodyne, cotati, CA, USA) with a 25µl sample loop and SPD-M20A photo diode array (PDA) detector (Shimadzu, Kyoto, Japan). During method development various mobile phases and different solvent systems were used. The mobile phase with Potassium di hydrogen phosphate (10mM, pH 7.0 adjusted with ortho□phosphoric acid) and methanol in ratio of 20:80 (v/v) at a flowrateof0.8ml/min was found to be optimum, which gave chromatogram with a sharp peak and good retention time. The mobile phase was filteredthrough0.45µmfilteranddegassedfor
10 minutes by sonication. The detection was carried out using a UV spectro photometric detectorat296nm and the run time was 7min. The peaks were identified by retention time

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

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

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 validated RP-HPLC method has been developed for determination of telmisartan and IS(Eposartan)in bulk and tablet dosage forms. Statistical analysis of the results shows that the proposed procedure has good precision and accuracy. This method is simple, reliable, accurate, linear, sensitive economical and reproducible. Hence this method can be suitable for routine quality control analysis of telmisartan and IS (Eposartan) in active pharmaceutical ingredient (API) and pharmaceutical preparations.

PROJECT INVESTIGATOR

PRINCIPAL

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

UTILIZATION CERTIFICATE

Academic Year: 2018-19

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 " Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms 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 Neuro Quant logy with same title in *DerPharmaciaLettre, 2011:3(5)318-32*

Sign of the Project Investigator
Department: Pharmacy

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

KP LABS
QUALITY- HONESTY-RELIABILITY

Date: 25/05/2018
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

KP 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.

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We are looking for a team of qualified faculty members at your college in Pharmacy Department who can work on "Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms by RP-HPLC" 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

KP LABS KOTHAPET, HYDERABAD KDPL

Authorized Signature

DATE: 26/05/2018
Hyderabad

To
The Manager
KP 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

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AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

Date: 26/05/2018

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

To
The Managing Director,
KP Labs,
Hyderabad,

Respected sir,

Sub: Project Development-Acceptance reg

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1. Dr. Nihar Ranjan Das (Project Investigator)
2. Dr. M. Rama Krishna (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,

Principal

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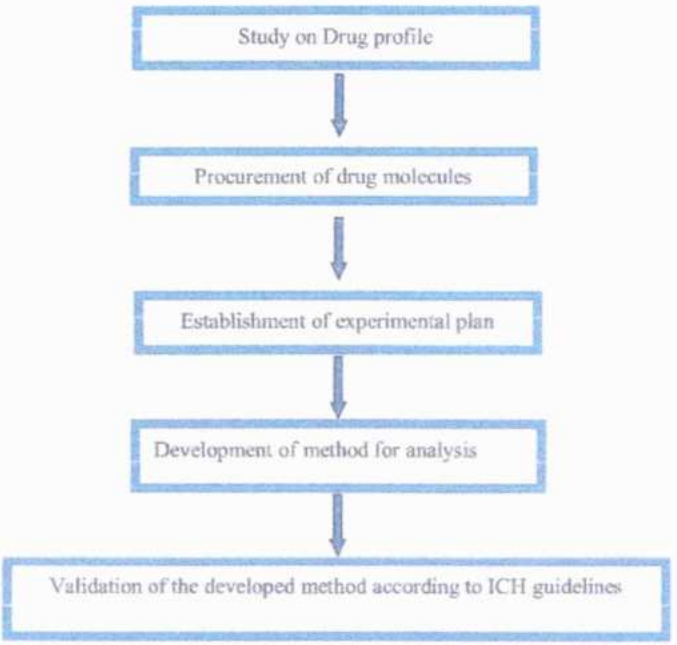
- PRINCIPAL
Avanthi's Institute of Pharmaceutical Scie
Gunthapally (V), Hayath Nagar (M
Ranga Reddy Dist.

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.

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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)
Capital Component		
1	Permanent Equipment (Located in lab/implementing organization) as per billing	30,000
2	Fabricated systems/demonstration models (located at beneficiary location)	30,000/-
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3	Travel	5,000/-
4	Overhead	--------
5	PC	---------
6	Printer and Scanner	5,000/-
B	Subtotal (General)	40,000/-
C	**Total cost of the project (A+B)**	1,00,000/-

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

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

KP LABS
QUALITY- HONESTY-RELIABILITY

WORK ORDER

Date: 01/06/2018

WO NO: WO/KP LABS/2018-19/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	10,000
2	Chemicals ,Reagents & Solvents	1	10,000
3	Equipments & Glassware	1	30,000
4	Compounds Characterization	2	10,000
5	Pharmacological evaluation	1	40,000
6	Total Cost in rupees		1,00,000/-

Rupees in words: one lakh rupees only

Work Oder Valid: One Year (FROM 01/06/2018 TO 31/05/2019)

KP LABS KDPL KOTHAPET, HYDERABAD

Authorized Signature

Terms& Conditions:

- Preparation of detailed drawings/Lay outs based on the reference design provided by the customer.
- Taking physical design for review and approval of our customer
- Submission of designs/lay outs for review and approval of our customer
- Incorporate any comments/feed back given by customer in the design/layouts
- Preparation of designs, lay outs, algorithms, part design, bill of materials for all designs.
- Preparation of built up designs, lay outs after completion of fabrication/Installation at site.

WORKING LOCATION: You're Premises

For KP LABS

PURCHASE MANAGER

Date: 02/06/2018

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

To
The Managing Director,
KP Labs,
Hyderabad,

Respected sir,

Sub: Analytical method development and validation of hydrochlorothiazide and Eposartan in API and its Dosage form by RP-HPLC

It gives us great pleasure to let you know that the project proposal for "Analytical method development and Validation for Cefixime and Dicloxacillin in combine Pharmaceutical Dosage forms 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,

Principal

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AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

Date: 01/12/2018

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

To
Proprietor,
KP 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.

I am looking forward to a quick response from your side.

Thanking you,

Principal

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES * ABDULLAPURMET *

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

PROJECT REPORT:

Introduction:

Hydrochlorothiazide (HCTZ) is a diuretic of the class of benzo-thiadiazine widely used in antihypertensive pharmaceutical formulations, alone or combination with other drugs. It decreases active sodium reabsorption and reduces peripheral vascular resistance. It is chemically known as 6-chloro-3, 4-dihydro-2H-1, 2, 4-benzothiadiazine-7-sulfonamide 1, 1-dioxide. HCTZ has been successfully used as single content Orin association with other drugs in the treatment of hypertension. Its molecular weight is 297.7**[1,2]** . The chemical structure of HCTZ is given in Eposartan (EPRO) is an antihypertensive drug whose chemical name is 4-({2-butyl-5-[2-carboxy-2-(thiophen-2-ylmethyl) eth-1-en-1-yl]-1*H*-imidazol-1-yl} methyl) benzoic acid. Its chemical structure is as given in figure2 below. It is a new antihypertensive drug and acts on the rennin-angiotensin system in two ways to decrease total peripheral resistance. Firstly, it blocks the binding of angiotensin II to AT1 receptors in vascular smooth muscle, causing vascular dilatation. This is followed by second step of inhibition of sympathetic nor epinephrine production, which further reduces blood pressure Presently, there is a combined pharmaceutical formulation of Eposartan mesylate (600mg)

Scope of the Project:

Chemicals and reagents:

The pharmaceutical grade pure samples of Hydrochlorothiazide (99.28%) and Eprosartanmesylate (99.55%) were supplied by Hetero laboratories, Andrapradesh, India. Methanol HPLC grade solvent and all analytical grade solvents were purchased from Merck Ltd, Mumbai, India. Potassium di hydrogen phosphate was procured from Qualigens Fine Chemicals, Mumbai, India.The HPLC grade water was obtained from a Milli-QRO water purification system, sonicated and used.

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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

Project planning and scheduling:

Standard stock solutions of1 mg ml^{-1} of HCTZ, and EPR were separately prepared by accurately weighing 100 mg of each of the standard drug into different 100 mL volumetric flasks. These were dissolved, sonicated and made up to the standard mark with mobile phase. A series of EPRO standard solutions in the concentration range of 20, 40, 60, 80 and 100 µg/ml were prepared followed by a suitable dilution of stock solution with the mobile phase. Likewise, a series of solutions in the concentration range of 5, 10, 15, 20 and 30 µg/ml were prepared for HTCZ.

The detection wavelength was fixed at 225 nm obtained from uv-overlay spectra of the two drugs. The standard calibration curves were constructed by plotting of graph of peak areas against the respective concentrations of standard drugs. The linear regression equations obtained arey = 0.0123X+0.0019(R^2=0.9984) and y=0.0034X0.0163 (R^2=0.9989) for HCTZ and EPRO respectively. The typical chromatogram recorded for standards are as shown in Fig.3.The retention time of standard HCTZ and EPRO were found to be 3.34 and 4.75 min, respectively.

Data collection and Analysis:

HPLC apparatus and conditions
Chromatography was performed using a JASCO HPLC 2080 model chromatograph (Japan) equipped with a PU-2080 isocratic delivery system (pump), UV-2075 detector (JASCO) with a Rheodyne 7725 injection valve with a 20µL loop volume. The analytical column was an Agilent xbd-reverse phase C18 column (150×4.6mm I.D; particle size 5µm). Data acquisition and processing was performed using JASCO BORWIN software (Japan).

Chromatographic separation was achieved at ambient temperature on a reversed phase column using a mobile phase consisting of a mixture of Buffer solution (20m M potassium di-hydrogen orthophosphate): Methanol in the ratio of 80:20. The pH of buffer was 4.85 ±0.05 and was used as such without any adjustment .The mobile phase so prepared was filtered through 0.22 nylon membrane filter and degassed by sonication. The Mobile phase was prepared freshly, filtered, sonicated before use and delivered at a flow rate of 1 mL / min and the detection was achieved at 225nm. The injection volume was 20 µl (fixed loop).

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Methodology

The standard procedures and conventions followed for preparation of the extracts, phyto chemical studies, isolation, purification of plant metabolites by using chromatographic techniques, compounds characterization using spectro photometric methods like GC-MS, NMR and FT-IR

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:

Linearity

The linearity for HPLC method was determined at five concentration levels ranging from 5-30µg mL^{-1} for HCTZ and 20-100 µg mL^{-1} for EPRO. The calibration curve was

Precision

The precisions of the analytical method were determined by repeatability (within-day) and Intermediate precision (between-day). Three different concentrations which were quality control samples (10, 20, 30 mg/mL) for HCTZ and (20, 40, 60) for EPRO were analyzed five times in one day for within-day precision and once daily for three days for between-day precision. The intraday and intraday precision showed a coefficient of variation ranged from 0.64% to 0.94% and from 0.78% to 1.25% respectively for HCTZ. The coefficient of variation of intraday and intraday precision for EPRO ranged from 0.65% to 0.98% and from 0.68% to 1.02%respectively. The results are shown in Table 2, and indicate that the method is precise.

Recovery

Recovery was determined by spiking the formulation with standards of each drug equivalent to 80,100, and 120 % of the amount originally present. % Recovery was calculated by comparing the area before and after the addition of the working standard. The percentage of individual drugs found in formulation, mean, standard deviation in formulation were calculated and presented in Table 3.The results of the recovery

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analysis were found to be 99.67 ± 0.21 to100.11 ± 0.15 for HCTZ and 99.59± 0.31 to 100.16± 0.27 for EPRO, and reported in Table 3. The results of analysis showed that the amounts of drugs found were in good agreement with the label claim of the formulation

Ruggedness and Robustness

Ruggedness test was determined between two analysts, instruments and columns. Robustness of the method was determined by small deliberate changes in flow rate, mobile phase pH and mobile phase ratio. The content of the drug was not adversely affected by these changes as evident from the low value of relative standard deviation indicating that the method was rugged and robust.

PROJECT INVESTIGATOR

PRINCIPAL

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UTILIZATION CERTIFICATE

Academic Year: 2018-19

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 " Analytical method development and validation of hydrochlorothiazide and Eposartan in API and its Dosage form 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 *DerPharmaciaLettre, 2011:3(5)318-325*

Sign of the Project Investigator

Department: Pharmacy

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Statement of Axis Account No :918010020435948 for the period (From : 20-12-2018 To : 21-12-2018)

Tran Date	Chq No	Particulars	Debit	Credit	Balance	Init. Br
		OPENING BALANCE			**297454.40**	
21-12-2018		By Clg 004093 240 Hyderabad		5000.00	302454.40	2568
21-12-2018		TRF/KP LABS/		500000.00	802454.40	3017
		TRANSACTION TOTAL	**.00**	**505000.00**		
		CLOSING BALANCE			**802454.40**	

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.

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Legends :

ICONN - Transaction trough Internet Banking
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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
EDC - Credit transaction through EDC Machine
SETU - Seamless electronic fund transfer through AXIS Bank