



# 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 2019-2020

S.NO	NAME OF THE PROJECT INVESTIGATOR/Chief Investigator	NAME OF THE FUNDING AGENCY	FUND PROVIDED(INR IN LAKHS)	DURATION OF THE PROJECT
1	1. Dr.K.Balaji 2.Dr. Nihar Ranjan Das 3.Dr. B.Manjula	CLINOXY SOLUTIONS	3.00	6 months



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



## CLINOXY SOLUTIONS PRIVATE LIMITED

CIN (U74910TG2021PTC155213)

Date: 05/12/2019  
Hyderabad

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

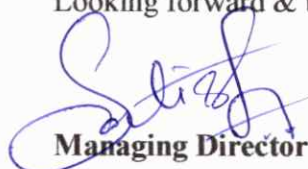
Dear Sir,

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 “Simultaneous Analysis of cytarabine and Daunorubicin in bulk form and marketed Pharmaceutical Combined dosage form by RP-HPLC-Pda Methods” analytical research and development and formulation research and development. If your college is interested to work in collaboration. We forward further documentation & I sincerely hope that we can keep the information confidential.

Looking forward & thank you.

  
**Managing Director**



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

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



**AVANTHI INSTITUTE OF  
PHARMACEUTICAL SCIENCES**

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



Date: 07/12/2019

HYDERABAD

To  
The Manager,  
Clinoxy Solutions Pvt Ltd

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

Respected Sir / Madam,

We thank you for sharing us the proposed project details.

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

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

Thank you once again.

Yours Sincerely

Principal



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

Copy to:

1. HOD of Pharmacy
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3. File



**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: 07/12/2019

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

To  
The Managing Director,  
Clinoxy Solutions Private Limited,  
Hyderabad,

Respected sir,

Sub: Project Development-Acceptance reg

It gives us great pleasure to let you know that the project proposal for "Simultaneous Analysis Of Cytarabine And Daunorubicin In Bulk Form And Marketed Pharmaceutical Combined Dosage Forms By Reverse Phase-High Pressure Liquid Chromotography-Pda Methods" 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 project development.

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

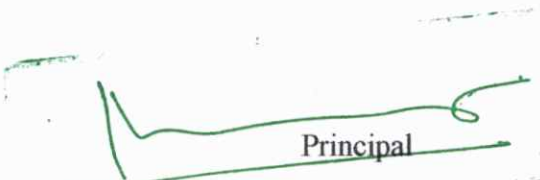
Please be assured that we will make every effort to complete the project as quickly as we can.

Thanking you,

Copy to:

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

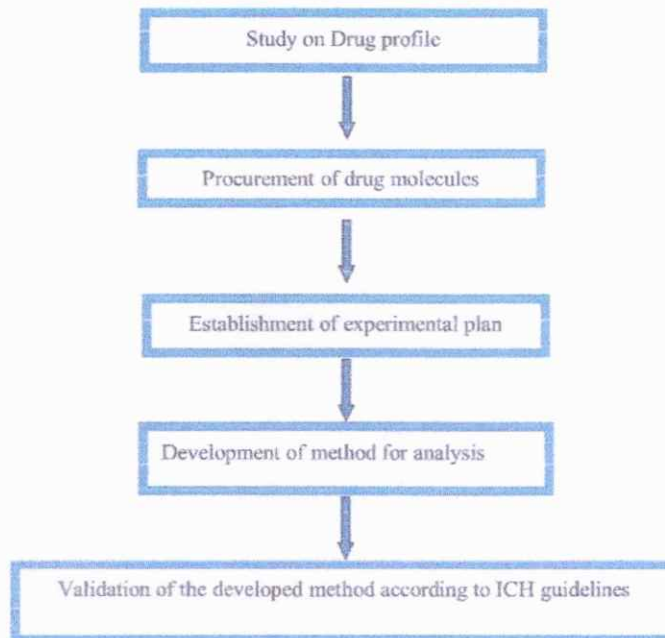


  
Principal

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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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Ranga Reddy Dist.



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

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

- I. **Project Cost: 3,00,000/-**  
II. **Contribution of consortium (if any):**  
III. **Total Budget (I+II): 3,00,000/-**



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



# CLINOXY SOLUTIONS PRIVATE LIMITED

CIN (U74910TG2021PTC155213)

## **WORK ORDER**

Date: 15/12/2019

WO NO: WO/COSPL/2019-20/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	30,000
2	Chemicals ,Reagents & Solvents	3	60,000
3	Equipments & Glassware	1	1,20,000
4	Compounds Characterization	2	50,000
5	Analytical method development	1	40,000
6	Total Cost in rupees	3,00,000/-	

Rupees in words: Three lakhs Rupees only

Work Oder Valid: One Year (FROM 15/12/2019 TO 14/12/2020)

### 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 Private limited

  
PURCHASE MANAGER



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

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



# AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES

(Approved by PCI, AICTE & Affiliated to JNTUH)

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



Date: 16/12/2019

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

To  
The Managing Director,  
Clinoxy Solutions Private Limited,  
Hyderabad,

Respected sir,

Sub: Simultaneous Analysis of Cytarabine and Daunorubicin in Bulk Form and Marketed Pharmaceutical Combined Dosage Forms By Reverse Phase-High Pressure Liquid Chromotography-Pda Method

It gives us great pleasure to let you know that the project proposal for "Simultaneous Analysis Of Cytarabine And Daunorubicin In Bulk Form And Marketed Pharmaceutical Combined Dosage Forms By Reverse Phase-High Pressure Liquid Chromotography-Pda Method" 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:

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PRINCIPAL

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





Date: 15/03/2020

Hyderabad

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

To  
Proprietor,  
Clinoxy Solutions Private Limited  
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

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AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES



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



## PROJECT REPORT:

### Introduction:

Cytarabine is a pyrimidine nonnucleoside analog used mainly in the treatment of leukemia, especially acute non-lymphoblastic leukemia, acute myelogenous leukemia, and meningeal leukemia. It is chemically 4-amino-1-[(2R,3S,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]pyrimidin-2-one. It has moderate emetogenicity which has been managed with antiemetic drugs [1]. Daunorubicin (Fig.2) is an anthracycline antibiotic that has antineoplastic activity and is used for the treatment of acute leukemia and acquired immune deficiency syndrome-related Kaposi sarcoma. It is chemically (1S,3S)-3-Acetyl-3,5,12-trihydroxy-10-methoxy-6,11-dioxo-1,2,3,4,6,11-hexahydro-1-tetracyclopenta[1,3-b]oxepin-2,3,6-trideoxy- $\alpha$ -L-lyxohexopyranoside. It is one among six Topo II inhibitors which is prescribed as highly antineoplastic drug in clinical use.

### 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:

#### Chemicals and reagents

Pharmaceutical grade cytarabine and daunorubicin were provided as gift samples by Spectrum Pharma Research Solutions, Hyderabad, and the marketed formulation is available as Vyxeos liposome for injection (cytarabine-65 mg and daunorubicin-29 mg per vial), for intravenous use. The formulation is not available in India. Hence, the injection was prepared with the available excipients in the laboratory using evaporation method and was extracted with the mobile phase during the study. Acetonitrile, ortho phosphoric acid, and HPLC grade water were purchased from Merck.

#### Instruments

Chromatography was performed on Waters HPLC 2695 equipped with PDA detector. The chromatographic separation was performed using Denali C18 (250 mm $\times$ 4.6 mm, 5  $\mu$ m). The data acquisition and integration were performed using Empower 2 software.



  
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### Chromatographic conditions

The developed method used a reverse-phase octadecylcolumn, Denali C18 (250 mm×4.6 mm, 5 μm), with mobile phase consisting of water (pH adjusted to 3 with orthophosphoric acid): acetonitrile (55:45) which was pumped at a flow rate of 1.0 ml/min and a detection wavelength of 240 nm using PDA detector.

### Preparation of diluents

The diluents used were water and acetonitrile in the ratio of 50:50.

### Preparation of standard solutions

The standard stock solution of cytarabine and daunorubicin was prepared by accurately weighing 16.25 mg of cytarabine and 7.25 mg of daunorubicin pure drugs and was transferred into a 25-ml clean dry volumetric flask, and then, 10 ml diluents was added and sonicated for 10 min and made up to the final volume with diluents. From the above stock solution, 1 ml was taken into a 10-ml volumetric flask and made up to the volume with diluents so as to get the final concentration of 65 μg/ml of cytarabine and 29 μg/ml of daunorubicin.

### Data collection and Analysis:

The proposed analytical method was validated for accuracy, precision, linearity and range, limit of detection (LOD) and limit of quantization (LOQ) in accordance with the ICH guidelines for analytical procedures Q2(R1).

### Methodology

#### Accuracy

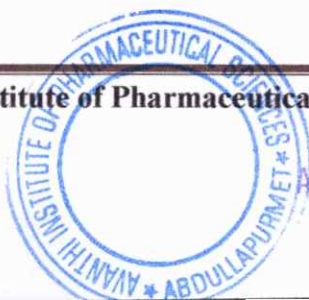
Accuracy of the developed method has been carried out by recovery studies by applying the standard addition method. A known quantity of drug substance corresponding to 50%, 100%, and 150% of the label claim of drug was added to pre-determined sample solution. Each set of addition was repeated three times. The accuracy was expressed as the percentage of analyses recovered by the assay.

#### Precision

The precision of the developed analytical method was carried out at target assay concentration level. Six determinations were performed and the results were expressed in terms of percent relative standard deviation (RSD).

#### Linearity and range

The linearity expresses the proportional relationship between concentration and responses. This was evaluated at six concentration levels in the range between 16.2–97.5 μg/ml and 7.2–





43.5 µg/ml for cytarabine and daunorubicin, respectively. A calibration curve was plotted by considering concentration against corresponding peak area, and using least square regression analysis, the correlation coefficient was determined.

LOD and LOQ of the developed method were calculated from the standard deviation of the y-intercepts and slope of the calibration curve of cytarabine and daunorubicin using the following formula

#### **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:**

##### Method validation

##### **Accuracy**

The percentage recoveries of cytarabine and daunorubicin at three different levels (50%, 100%, and 150%) were evaluated and are shown in Table 2. The results of accuracy specify that the recovery values were within the acceptance range of 98–102%. Hence, the developed method was accurate for the determination of specified drugs.

##### **Precision**

The precision of the method was verified by repeatability. The standard solution of cytarabine and daunorubicin was prepared at working concentration and was injected six times into the chromatographic system. The RSD was calculated and reported. The RSD values were found to be <2%. This clearly assured that the developed method was found to be precise, repeatable, and reproducible.

  
**PROJECT INVESTIGATOR**

  
**PRINCIPAL**

**- PRINCIPAL**



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



## UTILIZATION CERTIFICATE

Academic Year: 2019-20

Certified that the grant of Rs. 3,00,000 received to Avanthi Institute of Pharmaceutical sciences under the funding agency, for the Research Project entitled " SIMULTANEOUS ANALYSIS OF CYTARABINE AND DAUNORUBICIN IN BULK FORM AND MARKETED PHARMACEUTICAL COMBINED DOSAGE FORMS BY REVERSE PHASE-HIGH PRESSURE LIQUID CHROMATOGRAPHY-PDA METHOD" 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 December 2020, ||JournalDOI:10.36713, SJIF Impact Factor: 7.032,

Sign of the Project Investigator

Department: Pharmacy



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

**DCB BANK**

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रुपये Rupees Three Lakhs only

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₹ 300000/-

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Clinoxy Solutions

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**AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES**

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

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

Registered Mobile No :XXXXXXX5659

Registered Email ID:

PAN :AAATA3530B

Scheme :SB-TRUST/SOCIETY/NGO/GOVT

**Statement of Axis Account No :918010020435948 for the period (From : 29-05-2020 To : 30-05-2020)**

Tran Date	Chq No	Particulars	Debit	Credit	Balance	Init. Br
		<b>OPENING BALANCE</b>			<b>36944.48</b>	
29-05-2020		UPI/P2A/015006097743/BODINENT /State Ban/Maths e		360.00	37304.48	2738
29-05-2020		UPI/P2A/015028085238/ETIKALA /State Ban/Supply		4080.00	41384.48	2738
30-05-2020		UPI/P2A/015110132481/PRETOM CH/Paytm Pay/UPI		360.00	41744.48	2738
30-05-2020		UPI/P2A/015111908389/Mr BODUSU/Centraf B/T Racha		360.00	42104.48	2738
30-05-2020		UPI/P2A/015115171999/Ms GOWROJ/Indian Ba/UPI		360.00	42464.48	2738
30-05-2020		UPI/P2A/015118096385/R JASVANT/Paytm Pay/UPI		920.00	43384.48	2738
30-05-2020		UPI/P2A/015119803410/KONDRASI /Kotak Mah/UPI		360.00	43744.48	2738
30-05-2020		UPI/P2A/015121602088/J ARCHANA/Andhra Ba/UPI		360.00	44104.48	2738
30-05-2020		TRF/CLINOXY SOLUTIONS PVT LTD/		300000.00	344104.48	4267
		<b>TRANSACTION TOTAL</b>	<b>.00</b>	<b>307160.00</b>		
		<b>CLOSING BALANCE</b>			<b>344104.48</b>	

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

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

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

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

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

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

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

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

**Legends :**

- ICONN - Transaction trough Internet Banking  
 VMT-ICON - Visa Money Transfer through Internet Banking