



Number of MoUs, collaborations/linkages during the A.Y. 2019-20

| Sl. No. | Name of the collaborating agency / institution / industry / corporate house with whom the MoU / collaboration / linkage is made | Page No. |
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| 5 | Sionc Pharmaceuticals private limited | 9 |
| 6 | Biofact Research Private Limited | 10 |
| 7 | Unixperts Academic Consultants | 11-13 |
| 8 | National Research Development Corporation | 14-27 |
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| 10 | Veras Pharmaceuticals Pvt Ltd | 29 |
| 11 | University College of Pharmaceutical Sciences, AU | 30 |
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Y. Srinivasulu
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-46

Memorandum of Understanding (MOU)
Between

ZAINT HEALTH CARE PRIVATE LIMITED

and

VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

This Agreement made by this 17th day of March, 2020, between Zaint Health Care Private Limited located in Hyderabad and Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam.

Objective of the MOU

The objective of this Memorandum of Understanding (MOU) is:

- To promote the interaction between **ZAINT Health Care Private Limited** and **VIPT** which is mutually beneficial in the area of research and student training

Proposed Mode of Collaboration

- Sponsoring student projects, Internship and Industrial visits
- Sponsoring R& D projects, this may be carried out wholly or partly at **VIPT** or **ZAINT Health Care Private Limited**

Forms of Research and Development Programs

- In their own existing facilities. The performance of research individually by each party or concurrently with both parties in mixed groups at their own facilities.

Agreements for Research Collaboration

- The nature, scope and schedule of the Research collaboration.
- The form of research collaboration.
- The sponsoring of the research fund.

Signed In Duplicate

- This MOU is executed in duplicate with each copy being an official version of the Agreement
- By signing below, the parties acting by their duly authorized officers have caused this memorandum of understanding to be executed effective as of the day and year first above written. The agreement is valid for a period of one year.

S. Malayadri Somineni
Mr. Malayadri Somineni
Director
Zaint Health Care Private Limited,
Sy No: 228/E/B, Kucharam Village,
Medak District,
Hyderabad-502336, TG

Dr. Y. Srinivasa Rao
Dr. Y. Srinivasa Rao
Principal
Vignan Institute of
Pharmaceutical Technology
Beside VSEZ, Duvvada,
Visakhapatnam-530049, AP



Dr. Y. Srinivasa Rao
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49





Yeluri
Formulations Pvt. Ltd.

Factory : Sy. No. 296 / 7 / 6, IDA Bollaram, Sangareddy Dist. - 502 325.
Ph. - 08458 - 279 589, 279 584, Fax : 08458 - 279 354
Corp. Office : 3rd Floor, A.V.M. Towers, Beside Chutneys Restaurant,
Opp. KPHB Colony, Hyderabad - 500 072, Telangana
Ph. : +91 40 2389 9088, Fax : +91 40 2389 0559

**Memorandum of Understanding (MOU)
Between**

YELURI FORMULATIONS Pvt. Ltd.

and

VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

This Agreement made by this 7th day of March, 2020, between Yeluri Formulations Pvt. Ltd., Hyderabad and Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam.

Objective of the MOU

The objective of this Memorandum of Understanding (MOU) is:

- To promote the interaction between **YELURI Formulations Pvt. Ltd.** and **VIPT** which is mutually beneficial in the area of research and student training

Proposed Mode of Collaboration

- Sponsoring student projects, Internship and Industrial visits
Sponsoring R& D projects, this may be carried out wholly or partly at **VIPT** or **YELURI Formulations Pvt. Ltd.**

Forms of Research and Development Programs


- In their own existing facilities. The performance of research individually by each party or concurrently with both parties in mixed groups at their own facilities.


Agreements for Research Collaboration

- The nature, scope and schedule of the Research collaboration.
- The form of research collaboration.
- The sponsoring of the research fund.


Signed In Duplicate

- This MOU is executed in duplicate with each copy being an official version of the Agreement
- By signing below, the parties acting by their duly authorized officers have caused this memorandum of understanding to be executed effective as of the day and year first above written. The agreement is valid for a period of two years.


Dr. E. Nageshwar Rao
Director
Yeluri Formulations Pvt. Ltd,
Sy No: 296/7/6, IDA Bollaram,
Sangareddy Dist.-502325,
Telangana


Dr. Y. Srinivasa Rao
Principal
Vignan Institute of
Pharmaceutical Technology
Beside VSEZ, Duvvada,
Visakhapatnam-530049, AP

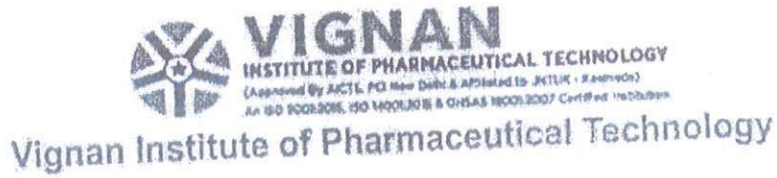



PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49



Memorandum of Understanding

Between



Jeju National University, Jeju, South Korea

Introduction

VIGNAN Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam, India and Jeju National University are mutually committed to the advancement of higher education and recognize the importance of fostering international communication and collaboration in addition to enabling our students to have a greater understanding of sensitivity to other cultures and global issues faced by our world community. We agree to the following Memorandum of Understanding as a statement of intent to work towards developing collaborative programs and fostering international cooperation.

Objectives

To accomplish the afore-mentioned goals, the parties agree to explore, encourage and facilitate programs and activities such as the following:

1. Exchange of academic and administrative staff;
2. Exchange of students;



G. Sivare Rao

PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
beside: VSEZ, Duvvada, Visakhapatnam-49

3. Accreditation of programs;
4. Language training programs;
5. Exchange of materials in education and research, publications, and academic information;
6. Joint research and meeting for education and research;
7. Other activities deemed appropriate.

Both institutions subscribe to a policy of equal opportunity and will not discriminate on the basis of race, gender, ethnicity, religion, national origin, or handicap.

This document constitutes the entire Memorandum of Understanding between the parties, and all prior discussions, agreements, and understandings, whether verbal or written, are hereby replaced by this Memorandum of Understanding.

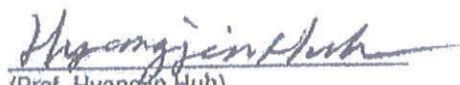
This Memorandum of Understanding will not be considered a binding contract creating legal and financial relationships between the parties but is designed as a means to facilitate and develop a genuine and mutually beneficial process for collaboration.

Subsequent to this agreement, the parties may choose to formalize the terms of cooperation and develop an agreement that will govern program operation.

This Memorandum of Understanding will take effect from the date of its signing and shall be valid for a period of five(5) years from that date unless prematurely terminated, revoked or modified by mutual agreement. The Memorandum of Understanding shall be automatically renewed for successive five-year periods unless either party gives the other written notice of its desire to either terminate or revise the Memorandum six months prior to the termination of a given five-year period.

Agreed:

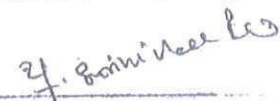
Jeju National University



(Prof. Hyangjin Huh)
PRESIDENT

Date: 28.02.2020

VIGNAN Institute of
Pharmaceutical Technology



(Dr. Y. Srinivasa Rao)
PRINCIPAL



Date: 28.02.2020

PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-46




PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49

Memorandum of Understanding

Vignan Institute of Pharmaceutical Technology (VIPT),

Beside VSEZ, Kapujaggarajupeta, Duvvada,, Gajuwaka,
Visakhapatnam, Andhra Pradesh 530049

And

ClinoSol Research Private Limited

D. No. 7-1-619/A/3/2, Gayathri Nagar Co-op Housing Board Society, East Srinivasa
Nagar Colony, Ameerpet, Hyderabad – 500038.

This Memorandum of Understanding (hereinafter called as the 'MoU') is entered into
on this the 28th day of February 2020, by and between:

Vignan Insitute of Pharmaceutical Technology, Duvvada the First Party
represented herein by its Principal / Director / Head of Institution **VIPT**

And

ClinoSol Research Private Limited, D. No. 7-1-619/A/3/2, Gayathri Nagar Co-op
Housing Board Society, East Srinivasa Nagar Colony, Ameerpet, Hyderabad – 500038,
The second party, and represented herein by its Mr. C.S. Mujeebuddin (Founder and
CEO), ClinoSol Research Private Limited, D. No. 7-1-619/A/3/2, Gayathri Nagar Co-
op Housing Board Society, East Srinivasa Nagar Colony, Ameerpet, Hyderabad –
5000383.

WHEREAS:

- A) First Party is a Higher Educational Institution named VIPT
- B) First Party & Second Party believe that collaboration and co-operation between
themselves will promote more effective use of each of their resources and
provide each of them with enhanced opportunities.
- C) The Parties intent to cooperate and focus their efforts on cooperation within
area of Skill Based Training, Education, Placement, Industrial Visit, Expert
Lecture.

C.S. Mujeebuddin



Dr. Srinivasa Rao
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49

CLAUSE 3: VALIDITY

3.1 This Agreement will be valid a period of 3 Years from the date of agreement being signed, it is expressly terminated by either Party on mutually agreed terms.

CLAUSE 4: RELATIONSHIP BETWEEN THE PARTIES

4.1 It is expressly agreed that First Party and Second Party are acting under this MOU as independent contractors, and the relationship established under this MOU shall not be construed as a partnership.

First Party

Signature-1

Y. Srinivas Rao

Name: Y. Srinivas Rao

Designation: principal

Date 28.02.20



Signature-2

K. V. Prasad Rao

Name: K. V. Prasad Rao

Designation: professor

Date 28.02.20

Second Party

Signature-1

C.S. Mujeebuddin

Name: C.S. Mujeebuddin

Designation: Founder and CEO

Date: 28th February 2020

Signature-2

G. Uma Priya

Name: G. Uma Priya

Designation: Director

Date: 28th February 2020

Y. Srinivas Rao
PRINCIPAL
VIGNANI INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duwada, Visakhapatnam-49



NOW THEREFORE, IN CONSIDERATION OF THE MUTUAL PROMISES SET FORTH IN THIS MOU, THE PARTIES HERETO AGREE AS FOLLOWS:

CLAUSE 1: CO-OPERATION

- 1.1 Both Parties are united by common interests and objectives, and they shall establish co-operation.
- 1.2 First Party and Second Party co-operation will facilitate effective utilization of the intellectual capabilities.
- 1.3 The parties shall co-operate with each other and shall as promptly as is responsibly practical, relevant agreement.

CLAUSE 2: SCOPE OF THE MoU

2.1 Industrial Training & Visits

Industry and Institution interaction will provide an insight into the latest developments / requirements of the industries; the Second Party to permit the Faculty and Students of the First Party to visit its group companies and also involve in Industrial Training Programs for the First Party. This will provide confidence & smooth transition for students work.

Guest Lectures

Second Party to extend the necessary support to deliver guest lecturers to the students of the First Party on the technology trends and in house requirements.

2.2 Placement of trained students

Second party will actively engage to help the delivery of the training and placement of the students of the first party on the technology trends and in house requirements.

- 2.3 There is no financial commitment on the part of the **Vignan Institute of Pharmaceutical Technology** the first party to take up any program mention in MoU. If there is any financial consideration, it will be dealt separately.

- 2.4 Both Parties to obtain all internal approvals, consents, permissions, and licenses of whatsoever nature required.

Memorandum of Understanding



C S Myeebhu Page 2 of 3

Y. Srinivas Rao
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49

**Memorandum of Understanding (MOU)
Between**

SIONC PHARMACEUTICALS PRIVATE LIMITED

and

VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

This Agreement made by this 28th day of February, 2020, between **Sionc Pharmaceuticals Pvt. Ltd.**, Visakhapatnam and **Vignan Institute of Pharmaceutical Technology**, Duvvada, Visakhapatnam.

Objective of the MOU

The objective of this Memorandum of Understanding (MOU) is:

- To promote the interaction between **Sionc Pharmaceuticals Pvt. Ltd.** and **VIPT** which is mutually beneficial in the area of research and student training

Proposed Mode of Collaboration

- Sponsoring student projects, Internship and Industrial visits
Sponsoring R& D projects, this may be carried out wholly or partly at **VIPT** or **Sionc Pharmaceuticals Pvt. Ltd.**

Forms of Research and Development Programs

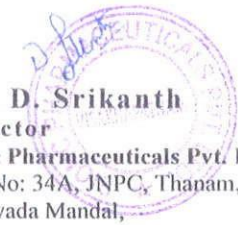
- The performance of research individually by each party or concurrently with both parties in mixed groups at their own existing facilities.

Agreements for Research Collaboration

- The nature, scope and schedule of the Research collaboration.
- The form of research collaboration.
- The sponsoring of the research fund.

Signed in duplicate

- This MOU is executed in duplicate with each copy being an official version of the Agreement
- By signing below, the parties acting by their duly authorized officers have caused this memorandum of understanding to be executed effective as of the day and year first above written. The agreement is valid for a period of two years.



Mr. D. Srikanth
Director
Sionc Pharmaceuticals Pvt. Ltd.
Plot No: 34A, JNPC, Thanam,
Parawada Mandal,
Visakhapatnam-531021, AP



Y. Srinivasa Rao
Dr. Y. Srinivasa Rao
Principal
**Vignan Institute of
Pharmaceutical Technology**
Beside VSEZ, Duvvada,
Visakhapatnam-530049, AP

Memorandum of Understanding (MOU)
Between
BIOFACT RESEARCH PRIVATE LIMITED
and
VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

This Agreement made by this 28th day of February 2020, between Biofact Research Private Limited located at Plot No.90/3, II Floor, Block D, APIIC (Industrial Park), Gajuwaka, Visakhapatnam, Andhra Pradesh 530012 and Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam.

Objective of the MOU

The objective of this Memorandum of Understanding (MOU) is:

- To promote the interaction between **BIOFACT** and **VIPT** is mutually beneficial area of basic research.

Proposed Mode of Collaboration

- Sponsoring student projects.
- Sponsoring R& D projects, this may be carried out wholly or partly at **VIPT** or **BIOFACT**.

Forms of Research and Development Programs

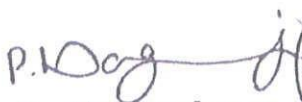
- In their own existing facilities — The performance of research individually by each party or concurrently with both parties in mixed groups at their own facilities.

Agreements for Research Collaboration

- The nature, scope and schedule of the Research collaboration.
- The form of research collaboration.
- The sponsoring of the research fund

Signed in Duplicate

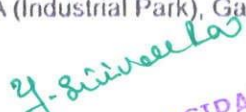
- This MOU is executed in duplicate with each copy being an official version of the Agreement
- By signing below, the parties acting by their duly authorized officers have caused this memorandum of understanding to be executed effective as of the day and year first above written.


Mr. P. Nagarjuna
Chief Operating Officer (COO)
BIOFACT RESEARCH PRIVATE LIMITED
Plot No.90/3, II Floor, Block D, APIIC (Industrial Park),
Gajuwaka, Visakhapatnam, Andhra Pradesh-530012.




Dr. Y. Srinivasa Rao
Principal
**VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY**
Beside VSEZ, Duvvada, Visakhapatnam,
Andhra Pradesh 530046




PRINCIPAL
**VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY**
Beside: VSEZ, Duvvada, Visakhapatnam-49

Memorandum of Understanding

Vignan Institute of Pharmaceutical Technology (VIPT),
Beside VSEZ, Kapujaggarajupeta, Duvvada, , Gajuwaka,
Visakhapatnam, Andhra Pradesh 530049

And

Uni Academic Consultants LLP
201, Eswar Plaza, Dwarakanagar Main Road, Visakhapatnam,
Andhra Pradesh 530016

This Memorandum of Understanding (hereinafter called as the 'MoU') is entered into on this the 28th February 2020, by and between:

Vignan Institute of Pharmaceutical Technology, Duvvada the First Party represented herein by its Principal / Director / Head of Institution **VIPT**

And

Uni Academic Consultants LLP (UNIXPERTS; 201, Eswar Plaza, Dwarakanagar Main Road, Visakhapatnam, Andhra Pradesh 530016. The second party, and represented herein by its Branch Manager in Visakhapatnam branch Mrs. Anitha Kommaraju and Mr. Ravada Naidu – Business Development Executive

WHEREAS:

- A) First Party is a Higher Educational Institution named VIPT
- B) First Party & Second Party believe that collaboration and co operation between themselves will promote more effective use of each of their resources and provide each of them with enhanced opportunities.
- C) The Parties intent to cooperate and focus their efforts on cooperation within area of Abroad Education, University Guest Lectures and Abroad Career Counselling.
- D) NOW THEREFORE, IN CONSIDERATION OF THE MUTUAL PROMISES SET FORTH IN THIS MOU, THE PARTIES HERETO AGREE AS FOLLOWS:

Memorandum of Understanding



Page 1 of 3

q - Srinivasa Rao

CLAUSE 1: CO-OPERATION

- 1.1 Both Parties are united by common interests and objectives, and they shall establish co-operation.
- 1.2 First Party and Second Party co operation will facilitate effective utilization of the intellectual capabilities.
- 1.3 The parties shall co-operate with each other and shall as promptly as is responsibly practical, relevant agreement.

CLAUSE 2: SCOPE OF THE MoU

2.1 Abroad Education

We will assist students in shortlisting universities and countries according to their profile. Our assistance also includes Scholarship and Visa assistance. We will also be updating students on Abroad Education through seminars at regular intervals.

Guest Lectures

The opportunity to get University Delegates from Various Universities of different countries to address the students about their Abroad Education Requirements and Queries.

- 2.2 There is no financial commitment on the part of the **Vignan Institute of Pharmaceutical Technology** the first party to take up any program mention in MoU. If there is any financial consideration, it will be dealt separately.
- 2.3 Both Parties to obtain all internal approvals, consents, permissions, and licenses of whatsoever nature required.

CLAUSE 3: VALIDITY

- 3.1 This Agreement will be valid a period of 5 Years from the date of agreement being signed, it is expressly terminated by either Party on mutually agreed terms.

CLAUSE 4: RELATIONSHIP BETWEEN THE PARTIES

- 4.1 It is expressly agreed that First Party and Second Party are acting under this MOU as independent contractors, and the relationship established under this MOU shall not be construed as a partnership.



Dr. Srinivas Rao
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam
Dr. Srinivas Rao



First Party

Signature-1

Name: Dr. Y. Srinivasa Rao

Date: 28/02/2020

Signature-2

Name: Mr. P.N. Mallikarjun

Date: 28/02/2020

Second Party

Signature-1

Name: Mrs. Anitha Kommaraju

Date: 28/02/2020

Signature-2

Name: Naidu Ravada

Date: 28/02/2020



Y. Srinivasa Rao

PRINCIPAL
VIGNANI INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49

MEMORANDUM OF AGREEMENT

BETWEEN



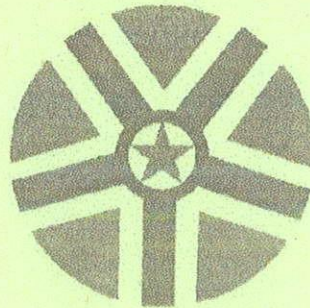
NATIONAL RESEARCH DEVELOPMENT CORPORATION

(An Enterprise of DSIR, Ministry of Science & Technology, Govt. of India)

20-22, ZAMROODPUR COMMUNITY CENTRE

KAILASH COLONY EXTENSION, NEW DELHI 110048

AND



VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

BESIDES VSEZ, KAPUJAGGRAJU PETA DUVVADA

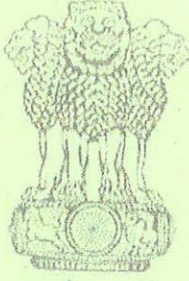
VISAKHAPATNAM -530049, ANDHRA PRADESH

February 2020



Dr. Sivase Rao

PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49



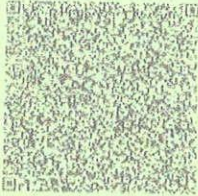
INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No. : IN-DL26255970972747S
Certificate Issued Date : 20-Feb-2020 12:24 PM
Account Reference : IMPACC (IV) dl857503/ DELHI/ DL-DLH
Unique Doc. Reference : SUBIN-DL85750361771452191219S
Purchased by : NATIONAL RESEARCH DEVELOPMENT CORPORATION
Description of Document : Article 5 General Agreement
Property Description : Not Applicable
Consideration Price (Rs.) : 0
(Zero)
First Party : NATIONAL RESEARCH DEVELOPMENT CORPORATION
Second Party : Not Applicable
Stamp Duty Paid By : NATIONAL RESEARCH DEVELOPMENT CORPORATION
Stamp Duty Amount:(Rs.) : 50
(Fifty only)



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MEMORANDUM OF AGREEMENT BETWEEN

NATIONAL RESEARCH DEVELOPMENT CORPORATION
(An Enterprise of DSIR, Ministry of Science & Technology, Govt. of India)
20-22, ZAMROODPUR COMMUNITY CENTRE
KAILASH COLONY EXTENSION, NEW DELHI 110048

AND

VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY
BESIDES VSEZ, KAPUJAGGRAJU PETA DUVVADA
VISAKHAPATNAM -530049, ANDHRA PRADESH



f. Srinivas Rao
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duwada, Visakhapatnam-49



MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (MOA) entered into on this 28th day of February 2020.

BETWEEN

National Research Development Corporation, an Enterprise of Department of Scientific & Industrial Research, Ministry of Science & Technology, Govt. of India, dealing within the meaning of and registered under the Companies Act, 1956, having its Registered Office at 'Anusandhan Vikas', 20-22, Zamroodpur Community Centre, Kailash Colony Extension, New Delhi-110 048 (hereinafter called 'NRDC' which expression shall include its successors in interest/business and permitted assigns) of the ONE PART;

AND

Vignan Institute of Pharmaceutical Technology established in 2006 affiliated to the JNTU Kakinada duly approved by the All India Council for Technical Education (AICTE), Pharmacy Council of India (PCI), Govt. of Andhra Pradesh and recognized as one of the premier pharmaceutical institutions in the State of Andhra Pradesh located at Besides VSEZ, Kapujaggraju Peta Duvvada, Visakhapatnam -530049, Andhra Pradesh (hereinafter called 'VIPT' which expression shall include its constituents, successors in interest/business and permitted assigns) of the OTHER PART.

WHEREAS 'NRDC' is a company established by the Government of India with the objectives, inter-alia of promotion, development, licensing and commercial exploitation of indigenous technology, know-how and inventions, including the technical and engineering know-how generated by various publicly funded R&D laboratories, universities and institutions. Since its inception, 'NRDC' has already transferred to industry and successfully commercialized a large number of technologies both in India and abroad.

WHEREAS, 'VIPT' is established with a view to provide job oriented professional courses in Pharmacy offering B. Pharm., M. Pharm., Pharm.D. programmes. The College is ISO9001 & ISO 14001 Certified for its safety and waste disposal methods employed. The college is presently one of the largest



2
Y. Suresh Rao
PRINCIPAL
VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY
Reside: VSEZ, Duvvada, Visakhapatnam-49



graduate, postgraduate and research institutions in Andhra Pradesh imparting quality pharmaceutical education.

AND WHEREAS 'VIPT' and 'NRDC' recognize the respective strengths of the two organizations and accordingly agree to cooperate in the development of technologies and their successful transfer to industry for commercial exploitation and socio-economic benefits.

'NRDC' and 'VIPT' shall be individually called 'Party' and jointly as 'Parties'

Now therefore, in consideration of the premises and mutual covenants hereinafter contained, the parties hereto agree as follow:

1. Subject to the conditions hereinafter contained 'VIPT' agrees to assign its technologies/Know-hows(s) to 'NRDC' free from encumbrances and developed by 'VIPT' for sole and absolute right of licensing and commercial exploitation by 'NRDC'.
2. 'VIPT' also agrees to provide 'NRDC/Licensee of 'NRDC' as the case may be, technical and engineering know-how relating to such Technology(ies) etc. consisting of documented technical information on the mode of working and using the same by an industry, as may be necessary to commercialize the said technology(ies) and associated patents/ designs/ copyrights/ trademarks etc. by 'NRDC' during the currency of this MOA in force.
3. 'VIPT' agrees to provide a demonstration of the technologies which are licensed by NRDC to the NRDC's licensee(s) at 'VIPT' on the scale at which the technologies have been developed by 'VIPT', within a period of 60 days of the date of signing of the licence agreement by the licensee with 'NRDC' to familiarize appropriately qualified personnel of the licensee and provide expert assistance to the licensee for implementation of the licensed invention/process/ product/ technology etc.
4. 'NRDC' agrees to give publicity to the availability of the technology(ies) assigned to it by 'VIPT' for commercial exploitation and also agrees to generate necessary market data/profiles, prefeasibility, feasibility and project reports, to promote speedy and effective licensing and commercialization of the technology(ies). 'NRDC' also agrees to associate the "VIPT" during negotiations for deciding the fee to be charged from the prospective licensees at the time of transfer of technology.



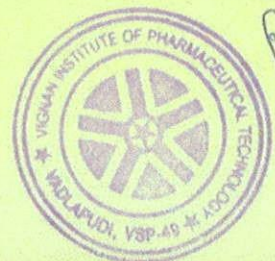
3
y. Srinivas Rao
PRINCIPAL
VIGNAN INSTITUTE
PHARMACEUTICAL TECHNOLOGY
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5. In consideration of the assignment, provision of technical information and documentation and technical services as aforesaid by 'VIPT', 'NRDC' agrees to remit to 'VIPT' 50% of the entire fees (Lumpsum Premium and Royalty) received by it from the licensees arising from and out of the said commercial exploitation of the technology(ies). The royalties payable to 'VIPT' shall continue for a fixed period agreed between 'NRDC' and the licensee, and 'NRDC' will apply its well established and time-tested methods of monitoring the extent of exploitation of the said Technology(ies) to ensure full and effective payment of royalties by the licensee concerned.
6. The premia and the royalty agreed upon by 'NRDC' and the licensee and the period of licensing will be finalised jointly by 'NRDC' in consultation with 'VIPT'.
7. In view of the cooperation provided for under this MOA, 'NRDC' agrees to advise 'VIPT' and render all possible assistance to 'VIPT' in the filing of patent applications (both in India and abroad) on technology(ies)), which 'VIPT' assigns or proposes to assign to 'NRDC' for licensing on the understanding that when the said patents are granted, 'VIPT' would assign those patents to 'NRDC' for commercial exploitation. All the expenses in obtaining the patent(s)/ design(s)/ copyright(s)/ trademark(s) etc. and maintaining in India on the invention(s)/ process(es)/ technology (ies) etc assigned to NRDC shall be borne by 'VIPT'.
8. In consideration of the covenants contained in the MoA, the 'VIPT' hereby agrees to keep indemnified the NRDC and its successors, executors, administrators, licensee(s) and legal representatives at all the times against all possible claims or demands, damages or any action or proceedings commenced by the VIPT or any person or persons through VIPT or against the VIPT or the NRDC before court, Tribunal or fora. All costs / legal expenses that may arise from such proceeding shall be borne by the VIPT.
9. 'NRDC' after due consultation with VIPT on case basis, hereby agrees, in case of revocation proceedings against a patent assigned to it by VIPT to protect technologies and in such a case, expenses will be shared in the same ratio of the revenue sharing i.e 50:50 between the "NRDC" and VIPT.
10. 'NRDC' agrees to take all measures in its control to oppose Indian Patent/ design/trademark application(s) filed by other parties which application(s)



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may be detrimental to the invention/ process/ product/ technology etc. assigned to 'NRDC' by 'VIPT' and 'VIPT' agrees to provide 'NRDC' all assistance in this regard. The cost involved shall be borne by 'VIPT'.

11. In the event of any of the aforesaid IPR(s) assigned to 'NRDC' being infringed and 'NRDC' initiating or instituting any legal proceedings, after due consultation with 'VIPT', to prevent such infringement, 'VIPT' agrees, if so required by 'NRDC', to render all assistance to 'NRDC'. The expenses in this regard will be shared in ratio of 50:50 between 'NRDC' and 'VIPT'. Similarly, the compensation awarded by the court will also be shared in the ratio of 50:50 by 'NRDC' and 'VIPT'.
12. In case 'NRDC' does not commercialize the assigned technologies within five years from the date of Assignment with 'VIPT', the parties shall meet and decide on the further course of action and if there are no immediate prospects of commercialization, the assigned technologies shall be reassigned to 'VIPT' and 'NRDC' shall not use the information relating to such technologies in any manner whatsoever, thereafter.
13. VIPT shall pay to NRDC as per the mutually agreed charges/ fees to NRDC for all of the consulting services required by VIPT on case to case basis.
14. Apart from the above-mentioned services: 'NRDC' will provide the following expert services on a mutually agreed terms and conditions on case to case basis:
 - 14.1 IPR Management: 'NRDC' shall provide all the assistance for assessing patentability through Patent search for prior art.
 - 14.2 University IPR Policy: 'NRDC' shall prepare "VIPT" IPR and Technology Management Policy on consultancy basis.
 - 14.3 Technology Transfer Cell: 'NRDC' shall mentor and guide "VIPT" Technology Transfer & IP Cell Policy on consultancy basis.
 - 14.4 IPR awareness / Training programme: Organizing one IPR awareness programme for one day to the faculty and students in the 'VIPT'.
 - 14.5 Techno-commercial evaluation of Technologies: Evaluation of technologies developed by faculty and students for their commercial potential.



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- 14.6 Market Research and Design Package: Creating Market Research (MR) and Basic Engineering Design Package (BEDP) for most prominent technologies developed by 'VIPT' to increase the potential of technology transfer.
- 14.7 Linkages with Research funding organizations: 'NRDC' shall assist faculty and students to get appropriate research funding from government departments such as DST, DBT, AICTE, etc. 'NRDC' will assist in drafting proposals and their evaluation before submitting to appropriate funding organization.
- 14.8 Mentoring Services: 'NRDC' shall provide hand holding and mentoring services through its panel of domain experts, and connect to advance laboratory facilities through its vast network of Labs, academic institutions and domain experts.
- 14.9 Facilitating industry visits of students: 'NRDC' will facilitate industry visits/training of 'VIPT' final year students in MSMEs/Corporates.
- 14.10 Linking to Start-up India Mission: 'NRDC' will facilitate 'VIPT' to establish student and faculty start-up. 'NRDC' shall provide suitable innovative technologies, give certificate for obtaining start up recognition, file patents under SIPP scheme of DIPP and link the students start-ups to appropriate funding agencies.
- 14.11 Incubation services: 'NRDC' shall assist and facilitate VIPT in setting up of incubation centers in their campus. In this endeavor NRDC will guide 'VIPT' in preparing the DPR, linking funding agencies and all the required hand-holding / mentoring.
- 14.12 Any other Techno-commercial services: If any other Techno-commercial services required by 'VIPT' and they fall within the ambit of 'NRDC' capabilities, 'NRDC' shall provide those services on mutually agreed terms and conditions.

15. Copyright and Intellectual Property

Means all proprietary inventions, processes, product designs, know-how or any other intellectual property of a Party or any other third party which is associated with such Party in development of any products and any other materials/application in any media and information, whether registered by such Party or not and here after acquired or developed by such Party. It also includes any service mark, commercial name, trademark, or trade name, whether registered by a Party or not or hereafter acquired or developed, that is associated with the each institution.



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The present course materials which are either in print, audio/video or electronic form belonging to and/or developed exclusively by the respective parties shall continue to remain the exclusive property of the respective parties

Any Intellectual Property in respect of any training materials which may be developed in future by respective organization for the use of students who are enrolled for these programmes shall be exclusively owned by the respective parties who created / developed it.

Intellectual property in the form of patents, copyrights etc. arising out of project work carried out jointly under these collaborative programmes will be decided in writing in advance before commencement of work.

Overall, both NRDC and 'VIPT' shall strive to protect the interest of other in the context of IPRs and agrees to do nothing which is viod of such laws and regulation of the land with reference to IPRs.

16. Use of Name

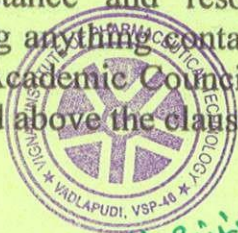
Either party may use other's name for the purpose of identifying above mentioned programme and shall not use, or be entitled to use, parties' name, trademarks, logos, trade name or any other intellectual property in any other way without the prior written consent or as may be authorized under a separate written consent. Upon termination by efflux of time, or prior determination thereof as provided for herein, of this MOA either party shall immediately stop using name, trademarks, trade name and logos, etc.

17. Termination

This MoA may be terminated by either of the parties by giving one month written notice to the other side sent through RPAD/Speed Post AD. In such an event, both parties shall complete their respective responsibilities outlined under this MOA which were agreed till such date of the notice of termination.

18. Matters not provided in the MOA

If any doubt arises as to the interpretation of the provisions of this MoA or as to matters not provided therein; the parties to this MoA may consult each other for each such instance and resolve those doubts in good faith and spirit. Notwithstanding anything contained herein above and decisions of the Board of Management, Academic Council or any other statutory body of the parties shall prevail over and above the clauses mentioned in the agreement.



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19. Force Majeure

- a) The parties to this MoA shall not be liable to each other for failure or delay in the performance of any of their obligations under this MOA for the time and to the extent such failure or delay is caused by riots, civil commotion, wars, hostilities between nations, government loss, orders regulations, embargos, action by the government(s) or any agency thereof act of God, storms, fires, accidents, strikes, sabotages, explosions; or other similar or different categories beyond the reasonable control of the respective parties to this MoA.
- b) In the event that either party is wholly or in part prevented from or hindered in carrying out or observing any of the terms or conditions of this MOA for any cause set forth herein above, such party shall give written notice to the other party by the most expeditious means as soon as possible after the occurrence of the cause relied on, giving full particulars of the reason for such prevention or hindrances, and the parties shall in good faith consult each other and take necessary measures for the resolution of the affairs so prevented or hindered.

20. Severability

If any provision of this MOA becomes or is declared illegal, invalid, or unenforceable, the provisions will be divisible from this MOA and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.

21. Confidentiality

It is envisaged that the Parties or any members of their respective Groups or any of their respective Agents may from time to time disclose Confidential Information relating to its current or proposed business to each other. In consideration of such Confidential Information being made available to both parties, the first party and the second party agree that any disclosure or dealings between the Parties will be subject to the terms and conditions of this Agreement. Both Parties will treat and keep all Confidential Information confidential and will not, without the Disclosing Party's prior written consent, directly or indirectly communicate or disclose (whether in writing or orally or in any other manner) Confidential Information to any other person other than in accordance with the terms of this Agreement (for the avoidance of doubt, this will also prohibit



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discussing the same with any Disclosing Party Group employees other than those involved in connection with the Project).

- a) Intellectual Property and Trademarks - Both the parties will continue with their respective trademarks including that of any improvements or work done at its own cost for this MOA.
- b) The obligations undertaken hereto shall not apply to any information obtained which is or becomes published or is otherwise generally available to the public other than in consequence of any willful or negligent act and such obligations shall survive the termination of this MOA.
- c) Parties may enter into a separate NDA if desired.

22. Headings

The heading used in the MoA is inserted for convenience / reference only and shall not affect the interpenetration of the respective clauses and paragraphs of this MOA.

23. Non-Waiver

The failure or neglect by either of the Parties to enforce any of the terms of this MoA shall not be construed as a waiver of its rights preventing subsequent enforcement of such provision or recovery of damages for breach thereof.

24. Assignment and Transfer

Any and all rights, duties and obligations of the parties under this MoA shall not be transferred or assigned by either party to any third party without prior written consent of the other party.

25. Representations and Warranties

The parties hereby represent and warrant to each other:

- a) That it is duly established and existing under the laws of jurisdiction stated against its name hereinabove and has the power and authority to sign this MoA and implement the Project agreed to herein.
- b) That it has the requisite legal power and authority to enter into this MOA, perform and comply with its duties and obligations hereunder.
- c) That this MoA constitutes legal, valid and binding obligations enforceable against it in accordance with the terms hereof:



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26. Address for Communication

Any notice or communication with reference to this MoA, unless otherwise specified herein shall be deemed to be validly sent, if dispatched by registered post acknowledgement due to the other party at the following respective address.

Contacting Person for "VIPT":

Dr. Y. Srinivasa Rao
Principal
Vignan Institute of Pharmaceutical Technology
Besides VSEZ, Kapujaggraju Peta Duvvada
Visakhapatnam -530049, Andhra Pradesh,
Ph: 0891-2511222, Mob: 9866399928
Email: viptvizag@gmail.com

Contacting Person for NRDC

Dr. H. Purushotham
Chairman and Managing Director
National Research Development Corporation
[An Enterprise of Department of Scientific & Industrial Research],
Ministry of Science & Technology, Govt. of India
20-22, Zamroodhpur Community Centre
Kailash Colony Extn., New Delhi - 110048,
Tel: +91-11-29240401-08 Extn. 210,
Direct: +91-11-29241212; Mob. No.91-9599229217
Fax: +91-11-29240409, 29240410
Email: cmdnrdc@nrdc.in

27. Either party may by a similar written notice to the other party change his / her aforesaid addresses.
28. If either party fails to fulfill its respective obligations as set out in the previous clauses of this MOA, both parties shall urgently consult one another with a view to correcting the default by the party concerned. If even thereafter the default is not rectified by the defaulting party, the other party may terminate this MOA by giving thirty (30) days advance notice in writing to the defaulting party provided that such termination shall not affect the rights of the parties to MOA which have been accrued prior to such termination.



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29. Upon such termination as set out in Clause 28:

- (i) The licence(s) granted by 'NRDC' shall continue for the period agreed between 'NRDC' and the licensee(s) concerned. Thereafter such Technologies assigned to 'NRDC' shall be reassigned to 'VIPT'. 'NRDC' also agrees not to grant any further licence(s) of the commercialised Technologies to any further party(ies). All aMOAnts accrued for payment to 'VIPT' by 'NRDC' on the date of termination shall be paid by NRDC after closing of annual account of 'NRDC'. As for payment accruing thereafter from such commercialised Technologies in respect of which licence(s) have already been granted by 'NRDC' and subsisting on the date of termination of this MOA, 'NRDC' will continue to remit them to 'VIPT' as if the MOA is in full force and effect; and
- (ii) The Technology(ies) assigned to 'NRDC' by 'VIPT' which have not been commercialized by 'NRDC' shall stand withdrawn and shall be reassigned to 'VIPT'. Thereafter 'NRDC' shall not use or cause other parties to use documents of such Technologies in any manner whatsoever.

30. If any dispute or difference arising out of this MoA shall be settled amicably through conciliation and the settlements so rendered between the parties in pursuance thereof shall be final and binding on the parties.

31. Arbitration

- (A) (i) If any dispute or difference arises between the parties hereto as to the construction, interpretation, effect and implementation of any provision of this MOA including the rights and liabilities or any claim or demand of any party against other or in regard to any other matter under this MOA but excluding any matters, decisions or determinations of which is expressly provided for in this MOA, such disputes or differences shall settled under the Rules of Delhi International Arbitration Center, New Delhi by Sole Arbitrator to be appointed out of the panel of Delhi International Arbitration centre (DAC) with the consent of all the parties failing which the aggrieved party shall approach to the court of competent jurisdiction for the appointment of the sole Arbitrator in accordance with the Arbitration and Conciliation Act, 1996 (as amended/modified from time to time) and the Rules framed there under for the time being in force (the Act) and the reference to arbitration shall be deemed to be submission within the meaning of the Act.



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- (ii) If however, any party does not make any claim or demand or raise any dispute or difference in terms of sub clause within one year from the date on which such demand or claim arises, then it shall be deemed to the parties have waived and abandoned such claim or demand or the right to raise such dispute or difference against the other party.
- (iii) (a) The venue of the Arbitration shall be at New Delhi.
- (b) Each party shall bear and pay its own cost of the arbitration proceedings unless the Arbitrator otherwise decides in the Award.
- (c) The provisions of this Clause shall not be frustrated, abrogated or become inoperative, notwithstanding this MOA expires or ceases to exist or is terminated or revoked or declared unlawful.
- (B) The High Court of Delhi at New Delhi and courts subordinate to it shall have exclusive jurisdiction in all matters concerning this agreement, including any matter arising out of the Arbitration proceeding or any Award made therein.
32. All works under this MoA shall be continued by VIPT and /or NRDC during the arbitration proceedings and their recourse to arbitration shall not bar to continue for the obligations of the other parties.
33. This MoA is valid for five (05) years from the date of signing but may be extended for further periods by mutual agreement between the parties.
34. This MoA shall become effective on and from the date it is signed.
35. This MoA has been made in two originals so that each party may have one original for their reference and record.



Y. Srinivas Reddy

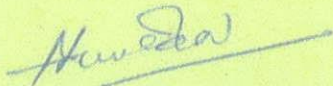
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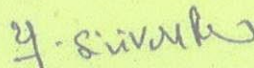


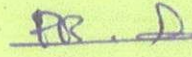
IN WITNESS WHEREOF, both the parties herein set their respective hands and seals on the day, month and year first above written in the presence of following witnesses :

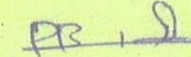
For and on behalf of
National Research Development Corporation, New Delhi

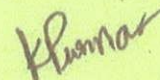
For and on behalf of
Vignan Institute of Pharmaceutical Technology, Andhra Pradesh

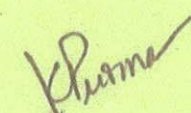

(Dr. H. Purushotham)
Chairman & Managing Director
Dr. H. Purushotham
Chairman and Managing Director
National Research Development Corporation
(An Enterprise of Department of Scientific & Industrial Research, Ministry of Science & Technology, Govt. of India)
Witnesses: 48


(Dr. Y. Srinivasa Rao)
Principal
PRINCIPAL
VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY
Beside: VSEZ, Duvvada, Visakhapatnam-49

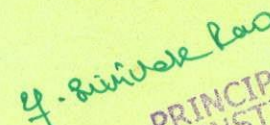
1. Signature: 
Name: Dr. P. Balakrishnaiah
Address: VIPT

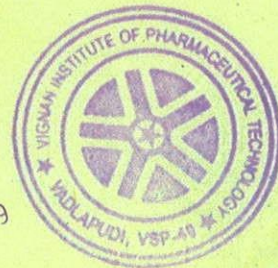
Witnesses:
1. Signature: 
Name: Dr. P. Balakrishnaiah
Address: VIPT

2. Signature: 
Name: Dr. K. Purina Naga Sree
Address: VIPT

2. Signature: 
Name: Dr. K. Purina Naga Sree
Address: VIPT




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**PHARMACON SOCIETY FOR
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Committed to Excellence in Pharmaceutical Care



VIGNAN

INSTITUTE OF PHARMACEUTICAL TECHNOLOGY
(Approved By AICTE, PCI New Delhi & Affiliated to JNTUK - Kakinada)
An ISO 9001:2015, ISO 14001:2015 & OHSAS 18001:2007 Certified Institution


Agreement of collaboration

Pharmacon Society for Pharmacy Practice (PSPP)
is proud to collaborate with
Vignan Institute of Pharmaceutical Technology, Vizag

Objectives of collaboration:

1. Augmenting the students learning with experts from industry.
2. Connect the students to Advisors, Coordinators and Mentors of PSPP from India, USA, Canada, Australia, Middle East, Ireland, UK, South Africa and Sweden.
3. Do interactive sessions and career awareness programs for students free of cost.
4. Offer guidance in doing Clerkship and Academic project effectively.
5. Offer guidance in implementation of Clinical Pharmacy Services during Internship.
6. Offer modules in Clinical Pharmacy, Clinical Research, Pharmacovigilance, Medical Writing, Clinical Data Management, Antimicrobial Stewardship, Medical Affairs and Research Methodologies for interested students at least possible cost.
7. Take up collaborative research projects.
8. Mentor Students in crafting successful career.

Collaboration will be valid for a period of 1 year from the date of confirmation i.e., 26-08-2019. It can be extended after a year with mutual agreement.


Dr. Karthik Rakam, Pharm. D
President
Pharmacon Society for Pharmacy Practice



Y. Srinivasa Rao
26/08/19
Dr. Y. Srinivasa Rao
Principal
Vignan Institute of Pharmaceutical Technology

Pharmacon Society for Pharmacy Practice (PSPP) is a society registered under Telangana Societies registration act 2001 with registration number 1586 of 2017.

Vignan Institute of Pharmaceutical Technology (VIPT) is one of the constituent colleges of Vignan Institutions well known for quality education with GLOBAL STANDARDS AND INDIAN VALUES. VIPT was established in 2006 with a view to provide job oriented professional courses in Pharmacy. VIPT offers B.Pharm., M.Pharm., Pharm.D. programmes.



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Beside: VSEZ, Duvvada, Visakhapatnam-49

Memorandum of Understanding (MOU)
Between

Veras Pharmaceuticals Pvt Ltd

and

VIGNAN INSTITUTE OF PHARMACEUTICAL TECHNOLOGY

This Agreement made by this 24th August 2018, between **Veras Pharmaceuticals Pvt Ltd** located at Vizianagaram and **Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam.**

Objective of the MOU

The objective of this Memorandum of Understanding (MOU) is:

- To promote the interaction between **Veras Pharmaceuticals Pvt Ltd** and **VIPT** is mutually beneficial area of basic research.

Proposed Mode of Collaboration

- Sponsoring student projects.
- Sponsoring R& D projects, this may be carried out wholly or partly at **VIPT** or **Veras Pharmaceuticals Pvt Ltd**

Forms of Research and Development Programs

- In their own existing facilities. The performance of research individually by each party or concurrently with both parties in mixed groups at their own facilities.

Agreements for Research Collaboration

- The nature, scope and schedule of the Research collaboration.
- The form of research collaboration.
- The sponsoring of the research fund

Signed In Duplicate

- This MOU is executed in duplicate with each copy being an official version of the Agreement
- By signing below, the parties acting by their duly authorized officers have caused this memorandum of understanding to be executed effective as of the day and year first above written and valid for three years.



Mr V.V.Rao
Director

Veras Pharmaceuticals Pvt Ltd

Sy no 56/ 11 to 14
Chelavuru-535005

Vizianagaram, Andhra Pradesh



Dr. Y. Srinivasa Rao
Principal

VIGNAN INSTITUTE OF
PHARMACEUTICAL TECHNOLOGY

Beside VSEZ, Duvvada,

Visakhapatnam, Andhra Pradesh 530049

Survey No. 56/11 to 14, Chelavuru, Vizianagaram - 535 005 A/P

e-mail : veraspharmaceuticals@gmail.com



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Identification, assessment and reporting of suspected Adverse Drug Reactions (ADRs) to Anti-retroviral therapy (ART) and Anti-tubercular therapy (ATT) in a community care centre at Warangal K.S.Arun Kumar*¹, Kranthi Yarlagadda ² and Wasim Feroz³.

¹Department of Pharmacy Practice, University College of Pharmaceutical Sciences, Andhra University, Visakhapatnam-530003, Andhra Pradesh, India.

²Pharmacovigilance specialist, Glaxo smith kline (GSK), Bangalore, Karnataka, India.

³Department of Pharmacy Practice, Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam, Andhra Pradesh, India

ABSTRACT

Adverse effects of drugs are the main source of morbidity and mortality among the outpatients and inpatients. The objective of the study was to identify, assess and report suspected Adverse Drug Reactions in patients who are diagnosed with Human Immunodeficiency Virus-Acquired Immunodeficiency Syndrome (HIV-AIDS) patients with and without Tuberculosis (TB). This was a prospective observational study conducted for a period of six months to explore the significant ADRs caused by Anti-Retroviral and Anti-Tubercular drugs in patients visiting community care centre at Warangal who are diagnosed with HIV-AIDS with or without Tuberculosis as co-infection. In our study we enrolled 144 patients and a total of 514 ADRs were identified in 125 patients. The most common ADR observed in our study was peripheral neuropathy in 61 patients, followed by vomitings, weakness, anorexia, myalgia, diarrhea and itching. The ART regimen Stavudine+Lamivudine+Efavirenz (STV+LMV+EFV) was found to be most commonly involved in about 138 ADRs, whereas the regimen Zidovudine+Lamivudine+Nevirapine (ZDV+LMV+NVP) was found to be having least incidence rate of ADRs. Causality assessment was made using WHO probability scale and Naranjo's Scale and 340 (66.14%) and 346 (67.31%) ADRs were classified into Possible respectively. Severity of ADRs were assessed using Hartwig scale and 376 (67.50%) ADRs were classified into Moderate and 138 (26.84%) into Mild ADRs. The findings of our study showed that a huge number of ADRs were experienced by the patients who are receiving ART and ATT which is a major cause for medication Non-compliance and discontinuation of the therapy. Therefore, close monitoring and reporting of ADRs is needed in these patients who are receiving ART and ATT.

Key words:

Adverse Drug Reaction, Anti-Retroviral Therapy, Anti-Tubercular Treatment, Human Immunodeficiency Virus-Acquired Immunodeficiency Syndrome (HIV-AIDS) and Causality.

Article History:

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*Corresponding Author

Name: K.S.Arun Kumar

Email: santhosh.pharmacy@gmail.com

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INTRODUCTION

Adverse drug reactions (ADRs) cause considerable mortality and morbidity¹. ADRs are defined by the World Health Organization as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."²

Globally, Adverse Drug Reactions (ADRs) account for 5% of all hospitalizations³. HIV stands for Human Immunodeficiency Virus and is different to AIDS, which is the advanced stage of HIV infection. This virus can be spread through infected blood, breast milk, semen, and anal or vaginal fluids contaminating the blood stream. This attacks the immune system by using the body's defence cells to replicate, simultaneously destroying the same cells that protect the body from illness. If HIV is not treated with antiretroviral treatment which works by preventing the virus from replicating - then the body is exposed to opportunistic infections which can cause serious illnesses^{4, 5, 6}. In 2016 more than 36 million

People had HIV globally. In 1990, the total number of deaths was estimated to be approximately 290,000; this increased to peak in 2005/06 at approximately 1.9 million. From then, the total number of deaths has been declined almost half, falling to around 1 million in 2016. Across this period, 15-49 year old have maintained the highest (and a consistent) share of around 74-75% of global deaths from HIV/AIDS⁷.

India has the third largest HIV epidemic in the world with 2.1 million HIV people. In 2017, HIV prevalence among adults aged 15-49 years was estimated 0.2%⁸.⁹ Among them, 79% of people were aware of their status and 56% were on antiretroviral treatment (ART)¹⁰. NACO is the governing body responsible for formulating the policy and implementing programmes in India for the prevention and control of the HIV epidemic. In 2017, India adopted "test and treat" following WHO guidance, which means anyone testing positive for HIV is now eligible for treatment, regardless of their CD4 count¹¹. Globally, 10 million people were estimated to have developed TB in 2017, 27% of whom lived in India. India has the highest proportion of MDR/TB cases at 24%¹².

METHOD DEVELOPMENT AND VALIDATION OF SELECTIVE AND HIGHLY SENSITIVE METHOD FOR DETERMINATION OF APIXABAN IN HUMAN PLASMA USING LIQUID CHROMATOGRAPHY-TANDEM MASS SPECTROMETRY

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ABSTRACT

Objective: The present research work aims to develop and validate a selective and highly sensitive method for the determination of apixaban in human plasma using liquid chromatography-tandem mass spectrometry (LC-MS/MS).

Methods: 200 µl of sodium heparin plasma samples were acidified and clean-up was performed by using solid-phase extraction (SPE). Apixaban 13C D3 was used as an internal standard (deuterated) to lower the relative matrix effects and a single step SPE was employed for sample clean up. 10 µl of SPE eluent was loaded onto Hypersil Beta Basic C18, 100×4.6 mm, 5 µm column for highly selective chromatographic separation using an isocratic mobile phase. 2 mmol/l ammonium acetate in water and acetonitrile were delivered by using a quaternary low-pressure gradient pump without premixing at a minimum flow rate of 0.50 ml/min.

Results: LC-MS/MS method was successfully developed and validated to demonstrate the lowest detection limit of 0.05 ng/ml and a linear dynamic range from 1-250 ng/ml with $r^2 > 0.99$. Method development and validation results proved that the method is selective and highly sensitive for the determination of apixaban in human plasma using LC-MS/MS.

Conclusion: Current method can be applied for both therapeutic drug monitoring (TDM) and pharmacokinetic (PK) study analysis.

Keywords: Human Plasma, Liquid Chromatography-Tandem, Mass spectrometry

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INTRODUCTION

Apixaban is a direct oral anticoagulant used in the management of thromboembolism and has gained importance as an alternative replacement to the vitamin K antagonists such as warfarin [1]. Therapeutic dose of apixaban results in nanogram level plasma concentrations. Therefore, it is evident to use a validated method for the estimation of apixaban in biological matrices like human plasma either for pharmacokinetic (PK) study analysis [2] or for therapeutic drug monitoring (TDM). LC-MS/MS is the only advanced technology that allows highly sensitive and selective-high throughput analysis even with low sample volumes. Moreover, it requires minimal and simple sample preparation procedures. Though several methods are available for determination of apixaban in human plasma or serum on LC-MS/MS [3-12], they were applied either for PK study analysis or for TDM but not for both. Therefore, the objective of the current study was to develop and validate a highly sensitive method with the lowest possible sample volumes, so that the same method can be further used for TDM also apart from PK study analysis.

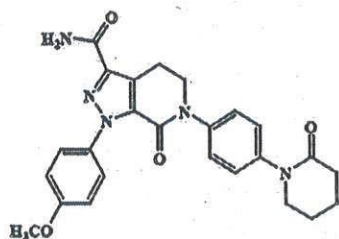


Fig. 1: Structure of apixaban

Apixaban is chemically described as 1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxopiperidin-1-yl) phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo [3,4-c] pyridine-3-carboxamide. Its molecular formula is C₂₅H₂₅N₅O₄, which corresponds to a molecular weight of 459.50. Apixaban has the following structural formula [13].

MATERIALS AND METHODS

Reagents and chemicals

Methanol (gradient grade), acetonitrile (gradient grade), orthophosphoric acid (guaranteed reagent grade) was purchased from Merck. Ammonium acetate (reagent grade) was purchased from Sigma Aldrich. Water (liquid chromatography-mass spectrometry grade) was used in-house from Milli Q system. Apixaban and apixaban 13C D3 were purchased from Vivan life sciences.

Preparation of standard solutions and quality control samples

Standard solutions of apixaban (100 µg/ml) and apixaban 13C D3 (100 µg/ml) were prepared in methanol. Intermediate stock solutions of both analyte and internal standard (10 µg/ml) were prepared in diluent (50% methanol in water) along with standard internal dilution (40 ng/ml). Nine level calibrators and four-level controls were prepared in human plasma containing sodium citrate as anticoagulant ranging from 1-250 ng/ml and 1-125 ng/ml respectively.

Sample preparation

50 µl of internal standard was added to 200 µl pre-spiked plasma samples and 50 µl of diluent has been added to the blank samples in prelabelled micro vials. Samples were vortexed to mix well. Samples were pretreated with 500 µl of 0.10% orthophosphoric acid, vortexed to mix. Apixaban and apixaban 13C D3 were subjected to



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REVISITING CARDIOPROTECTIVE ROLE OF CURCUMINOIDS: A COMPARISON OF CARDIAC OUTPUT, POSITIVE INOTROPIC, AND NEGATIVE CHRONOTROPIC EFFECTS IN ISOLATED PERFUSED FROG HEART PREPARATION

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ABSTRACT

Curcuminoids, a curcumin (C), demethoxycurcumin (DMC) and bisdemethoxycurcumin (BDMC) were isolated from *Curcuma longa* L. (*C. longa* L) by column chromatography and evaluated for relative cardioprotective potential in isolated frog heart preparation. Although DMC and BDMC are also principal curcuminoids but most of the studies reported on the cardioprotective role of *C. longa* L include C as effective and bioactive curcuminoid, thus DMC and BDMC were less explored. Based on our study, the results suggest that curcuminoids (C, DMC and BDMC) could exhibit cardioprotective activity as evidenced by improved hemodynamic variables such as cardiac output, positive inotropic and negative chronotropic effects. Our results demonstrated that the C has more significant effect on cardiac output, DMC exhibited enhanced negative chronotropic effect (increased heart rate),



Identification, assessment and reporting of suspected Adverse Drug Reactions (ADRs) to Anti-retroviral therapy (ART) and Anti-tubercular therapy (ATT) in a community care centre at Warangal K.S.Arun Kumar*¹, Kranthi Yarlagadda ² and Wasim Feroz³.

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ABSTRACT

Adverse effects of drugs are the main source of morbidity and mortality among the outpatients and inpatients. The objective of the study was to identify, assess and report suspected Adverse Drug Reactions in patients who are diagnosed with Human Immunodeficiency Virus-Acquired Immunodeficiency Syndrome (HIV-AIDS) patients with and without Tuberculosis (TB). This was a prospective observational study conducted for a period of six months to explore the significant ADRs caused by Anti-Retroviral and Anti-Tubercular drugs in patients visiting community care centre at Warangal who are diagnosed with HIV-AIDS with or without Tuberculosis as co-infection. In our study we enrolled 144 patients and a total of 514 ADRs were identified in 125 patients. The most common ADR observed in our study was peripheral neuropathy in 61 patients, followed by vomitings, weakness, anorexia, myalgia, diarrhea and itching. The ART regimen Stavudine+Lamivudine+Efavirenz (STV+LMV+EFV) was found to be most commonly involved in about 138 ADRs, whereas the regimen Zidovudine+Lamivudine+Nevirapine (ZDV+LMV+NVP) was found to be having least incidence rate of ADRs. Causality assessment was made using WHO probability scale and Naranjo's Scale and 340 (66.14%) and 346 (67.31%) ADRs were classified into Possible respectively. Severity of ADRs were assessed using Hartwig scale and 376 (67.50%) ADRs were classified into Moderate and 138 (26.84%) into Mild ADRs. The findings of our study showed that a huge number of ADRs were experienced by the patients who are receiving ART and ATT which is a major cause for medication Non-compliance and discontinuation of the therapy. Therefore, close monitoring and reporting of ADRs is needed in these patients who are receiving ART and ATT.

Key words:

Adverse Drug Reaction, Anti-Retroviral Therapy, Anti-Tubercular Treatment, Human Immunodeficiency Virus-Acquired Immunodeficiency Syndrome (HIV-AIDS) and Causality.

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INTRODUCTION

Adverse drug reactions (ADRs) cause considerable mortality and morbidity¹. ADRs are defined by the World Health Organization as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."²

Globally, Adverse Drug Reactions (ADRs) account for 5% of all hospitalizations³. HIV stands for Human Immunodeficiency Virus and is different to AIDS, which is the advanced stage of HIV infection. This virus can be spread through infected blood, breast milk, semen, and anal or vaginal fluids contaminating the blood stream. This attacks the immune system by using the body's defence cells to replicate, simultaneously destroying the same cells that protect the body from illness. If HIV is not treated with antiretroviral treatment which works by preventing the virus from replicating - then the body is exposed to opportunistic infections which can cause serious illnesses^{4, 5, 6}. In 2016 more than 36 million

People had HIV globally. In 1990, the total number of deaths was estimated to be approximately 290,000; this increased to peak in 2005/06 at approximately 1.9 million. From then, the total number of deaths has been declined almost half, falling to around 1 million in 2016. Across this period, 15-49 year old have maintained the highest (and a consistent) share of around 74-75% of global deaths from HIV/AIDS⁷.

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