MOU

Electrolab Private Limited

And

SCEs Indira College of Pharmacy

MOU

Date: 10/05/2017

Memorandum of Understanding between Electrolab (India) Pvt.Ltd and Indira College of Pharmacy

Electrolab and SCES' Indira College of Pharmacy (ICP) hereby agree to enter into a Memorandum of Understanding (MoU) for academic and professional collaboration with the purpose of mutual benefit. Electrolab has been in the business of pharmaceutical testing equipment for more than 30 years. ICP was established in 2006 and since then offers the courses of B.Pharmacy and M.Pharmacy. Both parties agree that giving exposure to the students to cutting edge technologies and practical projects will enable students to secure jobs as well as pursue entrepreneurship options. Both parties agree to the following terms

Placements and Corporate Relations:

a. Both organizations will work closely to come up with models of regular engagement between ICP students and faculties and Electrolab trainers, developers and project managers.
b. Electrolab will allow ICP undergraduates and post-graduates and faculty to visit their lab and attend technology conferences and events that Electrolab organizes for exposure and practical knowledge.
c. Looking at the expansion plan of Electrolab large pool of skilled manpower at different levels for small projects or for final hiring purpose will be required in the coming years. Electrolab will offer training and internship to the students of ICP for a period of 6 months to one year from commencement of the project and as per their performance may offer placement. Based on the duration of the project, a consolidated stipend, as mutually decided by Electrolab and ICP will be paid by Electrolab.

Research:

a. Electrolab and ICP will work together on joint research projects in areas of mutual interest. The projects designed or conceptualized by ICP faculty/ students will be executed partly at Electrolab and partly in the college after approval of the research proposal by Electrolab. Vice versa will also be possible.
b. The research work undertaken jointly by ICP and Electrolab will be published in reputed journals under the ownership of both the parties. In case of patentable research, both the parties would be the applicants of IPR and will share the benefits on equal basis.
c. Library and Lab facilities will be provided by ICP as and when required to Electrolab employees on a prior notice for the research work. For the use of sophisticated instruments and equipment, no charges will be applicable.
d. Electrolab will allow the students and faculty of ICP to use sophisticated instruments and equipment on a prior notice for the research work. This kind help extended by Electrolab will be duly

acknowledged by the students and faculty in their research publications and dissertation. The consumables such as solvents, reagents etc. will be procured by ICP.

e. Electrolab may donate some fabricated equipment and parts of dissolution testing apparatus to ICP for research purpose.

f. Consultancy:

a. ICP believes in inviting and involving Corporate Professionals for Board of Advisors, Guest Lectures, Workshops, Seminars and similar events for which expert/s are required for enhancing knowledge, skills and attitude of Faculty & Students. To achieve this objective, whenever possible, Electrolab will allow their professionals to visit ICP. ICP will also allow their faculty to visit Electrolab for sharing their knowledge and expertise in the area of interest for Electrolab.

g. Training:

a. Electrolab and ICP will conduct Faculty Development Programmes (FDP), Refresher Courses at ICP or Electrolab for which Electrolab will charge appropriately based on the number of participants in areas of mutual interest as mutually decided by the Director - Electrolab and Principal - ICP.

b. Electrolab will conduct meetups/events/ trainings at ICP. Electrolab may charge external participants some participant fees. ICP students shall be having a right to preferred discounts such as 20 % or 30 % in such meetups/events/trainings and the revenue will be split 70:30 between Electrolab:ICP.

c. All the promotional activities will be managed and marketing/faculty costs for meetups/events/ trainings at ICP shall be borne by Electrolab whereas ICP shall bear the infrastructure cost, admin costs and incidentals. Both parties will inform via email of the events and visits and seek prior permission from Principal - ICP and Director of Electrolab.

Contact Persons

Dr. (Mrs.) Madhur Kulkarni will be the contact person for ICP to initiate, manage or execute any joint activities between ICP and Dr. Neelam Sayed will be the contact person for Electrolab.

By: Director - Electrolab

Name: Mr. Aditya Marfatia

Date: June 13, 2017

By: Principal - ICP

Name: Dr. (Mrs.) Anagha Joshi

Date: 8/6/17

NON-DISCLOSURE AGREEMENT

THIS NON-DISCLOSURE AGREEMENT (this "Agreement") is made and entered into as of between Electrolab, Navi Mumbai and Indira College of Pharmacy(ICP), having its education setup at Niramay, S.No 89/2A, New Pune Mumbai Highway, Tathwade, Pune, Maharashtra – 411033.**Purpose: Electrolab And ICP wish to explore Opportunities in Training, Student Corporate Placement, Research, & consultancy of mutual interest and in connection with this opportunity wishes to execute this Non-Disclosure Agreement ("NDA").**

1. **Confidential Information**: Confidential information means any information disclosed by one party to the other, either directly or indirectly in writing, orally or by inspection of tangible or intangible objects, including without limitation documents, business plans, source code, software, hardware, application and uses of hardware and software, documentation, financial analysis, marketing plans, customer names, customer list, customer data. Confidential Information may also include information disclosed to a party by third parties at the direction of a Disclosing Party. Confidential Information shall not, however, include any information which the Receiving party can establish (i) was publicly known and made generally available in the public domain prior to the time of disclosure; (ii) becomes publicly known and made generally available after disclosure through no action or inaction of Receiving Party; or (iii) is in the possession of Receiving Party, without confidentiality restrictions, at the time of disclosure by the Disclosing Party as shown by Receiving Party's files and records immediately prior to the time of disclosure. The party disclosing the Confidential Information shall be referred to as "Disclosing Party" in the Agreement and the party receiving the Confidential Information shall be referred to as "Receiving Party" in the Agreement.

2. **Non-use and Non-disclosure**: The Receiving Party agrees not to use any Confidential Information for any purpose except to evaluate and engage in discussions concerning a potential business relationship between the parties hereto. Receiving Party agrees not to disclose any Confidential Information to third parties or to its employees, except to those employees who are required to have the information in order to evaluate or engage in discussions concerning the contemplated business relationship. The Receiving Party shall not reverse engineer, disassemble or decompile any prototypes, software or other tangible objects which embody the Disclosing Party's Confidential Information and which are provided to the Receiving Party hereunder.

3. **Maintenance of Confidentiality Information**: The Receiving Party agrees that it shall take all reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information. Without limiting the foregoing, Receiving Party shall take at least those measures that Receiving Party takes to protect its own most highly confidential information and shall have its employees, if any, who have access to Confidential Information sign a non-use and non-disclosure agreement in content substantially similar to the provisions hereof, prior to any disclosure of Confidential Information to such employees. The Receiving Party shall not make any copies of Confidential Information unless the same are previously approved in writing by the Disclosing Party. The Receiving Party shall reproduce the Disclosing Party's proprietary rights notices on any such approved copies, in the same manner in which such notices were set forth in or on the original. The Receiving Party shall immediately notify the Disclosing Party in the event of any unauthorized use or disclosure of the Confidential Information.

4. **No Obligation**: Nothing herein shall obligate either party to precede with any transaction between them, and each party reserve the right, in its sole discretion, to terminate the discussions contemplated by this Agreement concerning the business opportunity.

5. **No Warranty**: ALL CONFIDENTIAL INFORMATION IS PROVIDED "AS IS". NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS, IMPLIED OR OTHERWISE, REGARDING ITS ACCURACY, COMPLETENESS OR PERFORMANCE.

6. **Return of Materials**: All documents and other tangible objects containing or representing Confidential Information and all copies thereof which are in the possession of Receiving Party shall be and remain the

property of the Disclosing Party and shall be promptly returned to the Disclosing Party upon the Disclosing Party's request.

7. **No License**: Nothing in this Agreement is intended to grant any rights to either party under any patent, mask work right or copyright of Company, nor shall this Agreement grant Receiving Party any rights in or to Confidential Information except as expressly set forth herein.

8. **Term**: This Agreement shall survive for a period of 1year (renewable and extended up to 3 years) from the date of disclosure of the Confidential Information.

9. **Remedies**: The Receiving Party agrees that any violation or threatened violation of this Agreement will cause irreparable injury to the Disclosing Party, entitling the Disclosing Party to obtain injunctive relief in addition to all legal remedies.

10. **Miscellaneous**: This Agreement shall bind and inure to the benefit of the parties hereto and their successors and assigns. This document contains the entire agreement between the parties with respect to the subject matter hereof. Any failure to enforce any provision of this Agreement shall not constitute a waiver thereof or of any other provision hereof. This Agreement may not be amended, nor any obligation waived, except by a writing signed by both parties hereto. The parties have executed this Nondisclosure Agreement as of the date first above written.

[Electrolab]

By: Director

Name: Mr. Aditya Marfatia

Date: June 13, 2017

[ICP]

By: Principal

Name: Dr. (Mrs.) Anagha Joshi

Date: 8/6/17

SUMMARY

Shree Chanakya Education Society's

Indira College of Pharmacy, Pune

"Redefining Pharmacy Education"

NAAC : B++

Approved by PCI, AICTE, New Delhi, Affiliated to SPPU & MSBTE, Recognized by Govt. of Maharashtra

SUMMARY

Title: Activities carried out under MOU (Electrolab)				
S.No.	Name of the Activity	Year	Topic	Details
1	Research Projects	2017-2018	To develop rugged and reproducible drug release method for Acyclovir semisolid formulation using immersion cells	Collaborative Research project by Shrikant Potdar, M.Pharm student
2	Research Paper	2019-2020	In vitro release testing of Acyclovir topical formulations using immersion cell	Kulkarni, M et al, Assay & Drug Development Technology
3	Training Program	2017-2018	Principle and applications of Dissolution apparatus 3-7	Hands on training for F.Y. M.Pharm students and faculty
4	Training Program	2018-2019	Principle and applications of Dissolution apparatus 3-7	Hands on training for F.Y. M.Pharm students and faculty
5	Training Program	2019-2020	Principle and applications of Dissolution apparatus 3-7	Hands on training for F.Y. M.Pharm students and faculty
6	Training Program	2020-2021	Principle and applications of Dissolution apparatus 3-7	Hands on training for F.Y. M.Pharm students and faculty
7	Training Program	2021-2022	Principle and applications of Dissolution apparatus 3-7	M. Pharm
8	Poster presentation	2019	Ivrt of acyclovir semisolid formulations using immersion cells: Study of effect of test and formulation variables	19th International Symposium of controlled release society-India, Chapter

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				on Advances in Technology and Business Potentials of New Drug Delivery Systems

Dr. Anagha M Joshi
PRINCIPAL
Indira College of Pharmacy
Tathawade, Pune - 411 033

Indira College of Pharmacy * Pune *

Research Projects

ELECTROLAB (India) PVT. LTD.
Plot No. EL 23/24, T.T.C., Electronic Zone, M.I.D.C. Mahape, Navi Mumbai - 400 710. INDIA. Tel. : +91-22-4161 3131 Fax : 91-22-4161 3199

To Whomsoever It May Concern

This is to certify that Mr. Shrikant Potdar has undertaken his M.Pharm research project titled "To develop rugged & reproducible drug release method for acyclovir Semi Solid Formulation using immersion cells" at Electrolab under the able guidance of Dr. Neelam Sayed. The project was commenced on 17 July 2017 and completed on Feb 2018. During this tenure Shrikant was found to be sincere and hard working and his performance was satisfactory.

For Electrolab (India) Pvt Ltd.

Mr. Amit Marfatia
Managing Director

Electrolab (India) Pvt. Ltd. Navi Mumbai - 400710. India

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Tathawade, Pune - 411033.

Research Paper

In Vitro Release Testing of Acyclovir Topical Formulations Using Immersion Cells

Madhur Kulkarni,[1] Shrikant Pattar,[2] Abhijit A. Date,[2] and Aditya Marfatiya[3]

[1]Department of Pharmaceutics, Shree Chanakya Education Society's Indira College of Pharmacy, Pune, India.
[2]Department of Pharmaceutical Sciences, The Daniel K. Inouye College of Pharmacy, University of Hawaii at Hilo, Hilo, Hawaii, USA.
[3]Electrolab India Pvt. Ltd., Mumbai, India.

ABSTRACT

The objective of the study was to reinforce the applicability of the immersion cells for the in vitro release testing (IVRT) of topical formulations by using marketed acyclovir 5% cream formulation (Cream 1) as a model. The method employing the immersion cells was optimized by studying the effect of variables, such as membrane type, media temperature and volume, agitation speed, and cell size, on acyclovir release from the formulation. The in-house formulation similar to the qualitative and quantitative composition of Cream 1 and the other trial formulations with variable compositions were prepared and studied by using the immersion cells. Various other brands of acyclovir topical formulations available in the Indian market were also subjected to IVRT by using the optimized method. An increase in the media temperature from 32°C to 37°C and the stirring speed from 50 to 100 to 150 rpm led to an increase in the drug release. As the immersion cell size increased (0.5, 2 and 4 cm² surface area), the release rate also increased. Nitrocellulose membrane showed the highest drug release and Fluoropore™ the least. The optimized IVRT method could establish the differences in the drug release rates among the formulations with the altered compositions. The method could also prove its discriminatory potential for various marketed formulations. The immersion cell method could serve as a simpler, facile, and reliable aid during product development and also as a quality control tool in assessing stability, aging, and batch-to-batch uniformity of semisolid formulations.

Keywords: immersion cells, acyclovir, in vitro release testing, vertical diffusion cells, nitrocellulose membrane, enhancer cells

INTRODUCTION

In vitro release testing (IVRT) is an important quality and performance parameter for evaluation of the topical semisolid formulations. Similar to the solid oral dosage forms, IVRT of semisolids can help during product development stages in identifying the critical formulation and manufacturing variables. The release profile of the active ingredient from the formulation allows for optimization of the physical characteristics of the formulation during product development. A well-established, discriminatory IVRT method can also provide support during the stages of clinical development by establishing sameness as minor formulation changes are implemented during the course of clinical assessment. Besides aiding in product development, the IVRT can serve as a quality control tool to confirm batch-to-batch uniformity of the product. It helps in comparing the *in vitro* release profiles of test and reference products, though it is not expected to correlate or be predictive of *in vivo* bioavailability or bioequivalence. With the establishment of *in vitro* *in vivo* correlation for the developed method, the prediction of *in vivo* bioequivalence could also be possible.

A number of apparatuses, including vertical diffusion cells (VDCs), immersion cells, inverted immersion cells, flow-through cells, paddle over disk apparatus, and rotating cylinders apparatus, have been recommended for the IVRT of topical semisolid and transdermal formulations.[1–3] The IVRT has been made mandatory by the U.S. FDA since 2013 as one of the quality and performance parameters for the testing of semisolid formulations. As per the guidance of the U.S. FDA, the IVRT should be performed in a manner described in USP General chapter <1724> Semisolid Drug Products.[4] The USP indicates the use of one of the three types of cells—VDCs, commonly known as Franz diffusion cells; immersion cells, also known as Enhancer cells; and Flow-through cells or USP Type 4 apparatus. Of these, VDCs are explored the most for developing and validating IVRT of formulations of many drugs; whereas flow-through cells have been explored the least for this purpose. The immersion cell method employs the routine USP Type 2 dissolution apparatus and needs only a set of flat-bottom flasks of 200 mL capacity and mini paddles to conduct the IVRT. Uniform and accurate loading of the semisolid formulation in the immersion cells is easily possible

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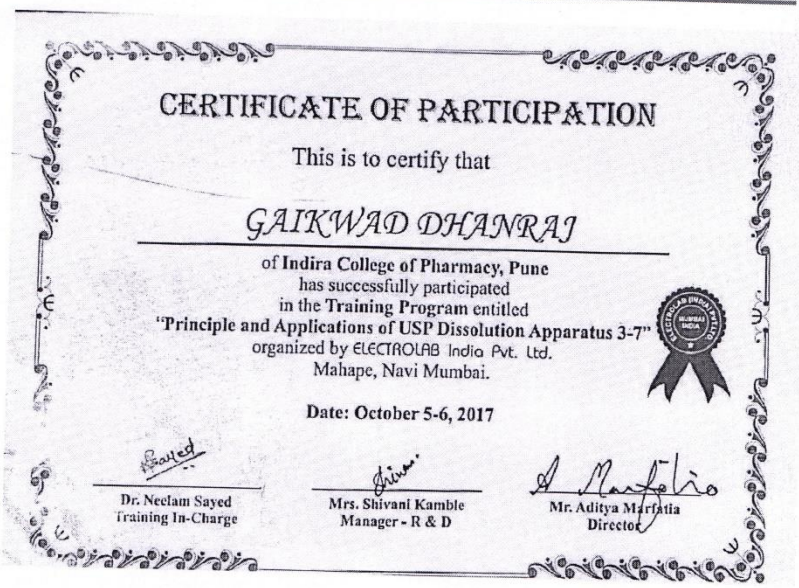
Training Program



CERTIFICATE OF PARTICIPATION

This is to certify that

GAIKWAD DHANRAJ

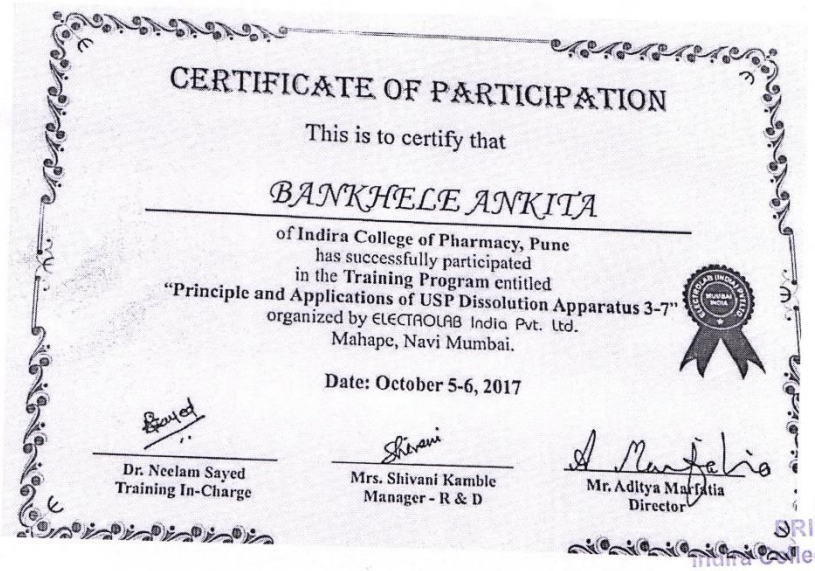
of Indira College of Pharmacy, Pune
has successfully participated
in the Training Program entitled
"Principle and Applications of USP Dissolution Apparatus 3-7"
organized by ELECTROLAB India Pvt. Ltd.
Mahape, Navi Mumbai.

Date: October 5-6, 2017

Dr. Neelam Sayed
Training In-Charge

Mrs. Shivani Kamble
Manager - R & D

Mr. Aditya Marfatia
Director



CERTIFICATE OF PARTICIPATION

This is to certify that

BANKHELE ANKITA

of Indira College of Pharmacy, Pune
has successfully participated
in the Training Program entitled
"Principle and Applications of USP Dissolution Apparatus 3-7"
organized by ELECTROLAB India Pvt. Ltd.
Mahape, Navi Mumbai.

Date: October 5-6, 2017

Dr. Neelam Sayed
Training In-Charge

Mrs. Shivani Kamble
Manager - R & D

Mr. Aditya Marfatia
Director

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Indira College of Pharmacy Pune

Training Program

CERTIFICATE OF PARTICIPATION

This is to certify that

Kapale Madhavi

of Indira College of Pharmacy, Pune
has successfully participated
in the Industrial Visit and Training Program entitled
"Principles and Applications of USP Dissolution Apparatus 1-7"
organized by ELECTROLAB India Pvt. Ltd.
Mahape, Navi Mumbai.

Date: February 28th and March 1st, 2019

Dr. Namita Varde
Training In-Charge

Mrs. Shivani Kamble
Manager - R & D

Mr. Aditya Marfatia
Director

ELECTROLAB

CERTIFICATE OF PARTICIPATION

This is to certify that

Mr. Hrishikesh Motilal Mahale

Has successfully attended the
two days hands-on training workshop on
USP dissolution apparatus - Type 1-7
held on 11-14th May, 2022

Mr. Amit Marfatia
Director

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Indira College of Pharmacy Pune

Poster Presentation

Poster Presentation

P 046

IVRT OF ACYCLOVIR SEMISOLID FORMULATIONS USING IMMERSION CELLS: STUDY OF EFFECT OF TEST AND FORMULATION VARIABLES

Kulkarni M., Potdar S., Syed N., Marfatiya A.
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Keywords: Acyclovir, Immersion Cells, IVRT, semisolids

Aim: The aim of the present work was to study the impact of test and formulation variableson in vitro release of acyclovir from its semisolid formulations employing Immersion Cells.

Objectives- 1. Study of variables like membrane, stirring rate, media volume, temperature, and size of Immersion cells on in vitro release of acyclovir from the innovator cream formulation2. Study of impact of formulation variables such as solvent concentration, method of preparation, consistency, cosolvent concentration on in vitro release of acyclovir 3. Comparison of acyclovir release from various marketed formulations using the optimized IVRT method

Methodology: Immersion Cells ™ type A were used for optimizing IVRT method of acyclovir topical formulations. The USP Apparatus Type 2 (Electrolab EDT 081x) equipped with flat bottom 200 ml capacity flasks and mini spin paddleswas used in the study. Alkaline borate buffer pH 9.2 was chosen as a receptor fluid. Effect of following variables was assessed on the release of acyclovir from its marketed cream formulation (Acivir®- Cipla). Membrane type - Durapore™/Nitrocellulose/ Fluropore™; Media volume- 150 mL/200 mL, Media temperature – 32° C/ 37° C, Paddle speed – 50/100/150 RPM, Immersion cell size- 0.5/2/4 cm^2. Different formulations prepared with changes in the compositions were F1 with same formula as marketed one (Acivir-Cipla), F2 with the same formula but without the homogenization step. F3 without the use of solvent (Propylene glycol), F4- with higher solvent conc , F5-with altered composition of oil phase. F6 & F7- with polyethylene glycol 200 & 4000 respectively as solvents instead of propylene glycol. All the formulations were subjected to IVRT using Nitrocellulose membrane, 200 mL of the borate buffer maintained at 32° C and agitated at the rpm of 150. The cream was loaded in the immersion cell of 2 cm^2 and the study was performed for 6 h duration with withdrawal of 5 mL aliquots at 0.25, 0.5, 1, 2, 4 and 6 h intervals. Equal volume of the fresh receptor fluid was replaced at every sampling interval. The in vitro drug release rate was computed. Various marketed formulations of acyclovir were subjected to the IVRT using the method mentioned above. The release rates were compared statistically by one-way ANOVA at $p \leq 0.05$ using Graphpad prism software (version)

Results: Nitrocellulose membrane showed greater release of the drug compared to Durapore and Fluoropore. With the increase in the agitation speed from 50 to 100 to 150, the amount of acyclovir release increased linearly. Temperature of the receptor fluid had a significant impact on the release of the drug with higher temperature showing greater release. Media volume of 150 mL showed greater release per mL as compared to 200 mL owing to lesser dilution. As the cell size increased, the drug release also increased proportionately. The media volume of 200 mL at 32°C with 150 rpm paddle speed and cell size of 2 cm^2 employing Nitrocellulose membrane was considered as the optimum method for further studies.
The method was found to be discriminatory with the formulation F4 containing higher solvent concentration showing better release. Absence of propylene glycol in the formulation F3, F6 and F7 reduced the drug release which could be attributed to reduction in the solubility of the drug in the vehicle affecting its diffusion. Drug release from formulation F1 found to be similar to that of the marketed cream. Lack of homogenization of formulation F2 affected the drug release which was well detected by the developed method. Formulation F5 with altered viscosity did show the difference in the release pattern. Finally, the comparison of drug release from various marketed cream formulations showed similar