

*Certificate course on “Reverse engineering approaches in pharmaceutical products”*

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**GRADUATE SCHOOL OF PHARMACY**

**offered**

**Certificate Course**

**On**

**“Reverse engineering approaches in pharmaceutical  
product development”**



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### **About GTU-GSP:**

Gujarat Technological University is a State University established in year 2007 to harmonize the technical education and to bring technical institutes under a single university by our Visionary Prime Minister Shri Narendra Modi, during his tenure as chief Minister of Gujarat. Gujarat Technological University-Graduate School of Pharmacy (GTU-GSP) was established in year 2017 with a vision to emerge as a globally recognized premier Pharmacy Institute in Teaching, Research, Innovations, Consultancy and Entrepreneurial Training in Pharmaceutical Sciences.

### **About this Course:**

GTU-GSP is offering a certificate course on Reverse engineering approaches in pharmaceutical product development. This certificate course is meant for fresh M. Pharm students, PhD students, Industry Personnel, life sciences students, and other eligible enthusiastic individuals who are keen to pursue their career in the area of formulation development in a pharmaceutical company. The course is meant to apprise those who are aware of certain basic nitty-gritties of formulation development, but lack in depth knowhow of how to proceed for formulation development and understand the findings obtained from experimental data of different analytical instruments. This is an advanced certification course with emphasis on understanding how, when and why of designing a reverse engineering protocol for different pharmaceutical formulations, with several case studies for better understanding of the concept. Beginning from basics pertaining to solid state changes which impacts formulation, to understanding the results of different analytical instruments used in the characterization, will be also included as a part of this certificate course. The end objective being, to educate one about the much-needed basic concepts of reverse engineering and how it could be used to deduce the active, inactive components and process used by innovator during formulation development to enable design of generic product. Further to ensure

the participants, clear the qualifying exam for obtaining the certification, the institute will be offering proper training materials which will be provided without any extra cost.

### **Scope and objective of the Course:**

India being one of the pioneers in the generic formulation development, the present course will be of tremendous help in understanding the science behind reverse engineering of different solid oral pharmaceutical formulations. Unfortunately, the timelines for generic formulations requires that the reverse engineering aspects are thoroughly understood at the beginning itself, to avoid any last moment failure. Thus, the scope of this course is for everyone who is presently working in the field of formulation development or wants to pursue the same as career opportunity in near future.

The prime objective of this course is to offer the much-needed basic concepts of reverse engineering and how it could be used to deduce the active, inactive components and process used by innovator during formulation development.

### **Target Audience:**

The present certification programme is designed for undergraduate (in final year of degree course) Postgraduate, PhD students etc. who are keen to understand the basics of reverse engineering before taking the leap into their professional career. This course is also apt for working professionals in full time employment who want to update their knowledge and gain required skills and attitude in the area, in order to become a certified professional in the domain. Further the understanding of results obtained from different analytical instruments like DSC, TGA, SEM, XRD will further enhance their understanding of these results and provide the much-needed leverage to their professional growth. Besides the theoretical aspects, the course is designed in a way to have several case studies to ensure better understanding of the concepts and to facilitate in acquiring

maximum output from certification programme. The training program on “Reverse engineering approaches in pharmaceutical product development” imparted by GTU-GSP is approved and certified by GTU, Government of Gujarat.

### **Course Structure:**

Duration of Course	3 months
Total hrs	30
Course Credit (if applicable)	2
No of seats	30
Mode	Being an e course the program will be executed on weekends, through online lectures, interactive discussions, and e-submission of assignments
Fees	Rs. 10000/- for Indian nationals and 200 USD for overseas professionals

### **Course Content:**

<b>Module</b>	<b>Content</b>	<b>Hrs (Approx.)</b>
1	Introduction to reverse engineering studies	1
2	Levels of solid state( molecular, particulate and bulk)	2
3	Implication of changes in levels of solid state on formulation development; impact of polymorphic form, crystal habit, shape, size distribution, bulk density, flow properties etc.	3
4	Analytical instruments and techniques used to study changes in solid state; choosing the right technique, principle of operation, interpretation, case studies	4
5	Thermal methods and its application in reverse engineering with case studies	4
6	Role of microscopic techniques in reverse engineering and relevant case studies	3
7	XRD: an important tool in reverse engineering of API polymorphic form and relevant Case studies	3
8	Identifying the manufacturing process used in Innovator product of a solid oral formulation and relevant case studies	4

9	Understanding the importance of dissolution studies on reverse engineering , importance of multimedia dissolution, F2 matching, biorelevant dissolution media, case studies	3
10	Collating the results of different experiment for effective reverse engineering, understanding the pros and cons and regulatory aspects of reverse engineering	3
<b>Total Hours</b>		<b>30</b>

### **Expected Course Outcomes:**

After completion of course, the attendee shall be able to

CO1	Explain levels of solid state of a pharmaceutical product
CO2	Describe impact of changes in levels of solid state and its correlation with reverse engineering studies on product performance
CO3	Understanding the results of Thermal, Microscopic, spectroscopic techniques of a given product, for reverse engineering
CO4	Adept in designing a reverse engineering protocol for a given solid oral product /formulation, to create a generic version of the same product, for filing to regulatory agencies

### **Eligibility:**

Any Life sciences graduate/B Pharm/ M. Pharm, MSc in science disciplines/ any diploma /degree holders. Working professionals of any of the following industry types Drugs manufacturing, Medical Device, Pharmaceutical Industry, Cosmetic Manufacturing, Biotechnology or any related industry are highly encouraged to apply for the certification.

(**Note:** Students who are in final year B pharm of their graduation course are also eligible to apply for this certificate course)

### **Registration:**

The registration dates for this certification run by the institute are updated timely on the webpage. Effective E-learning tools incorporated into the design of the webpage make the certification lectures, videos and study material easily

accessible. This gives huge window of self-regulated and self-paced performance to the participants. After registration confirmation by the institute, required study resources, assessment test papers will be dispatched to the participants. This study material is considered sufficient for the preparation of the certification exam. However, the participants should feel free to go through other study resources as well. The certification examination will be notified after 3 months of the registration.

### **Course Fee:**

Rs. 10000/- for Indian nationals and 200 USD for overseas professionals. This covers the certification registration fee and examination fee.

### **Evaluation, Assessment & Certification:**

All the participants are expected to appear for online assessment. After successful completion the participants will be certified in “*Reverse engineering approaches in pharmaceutical product development*” by GTU. For all the above-mentioned elaborate study resources, Assessment test papers and case studies would be provided by the Institute from time to time. All the details will be updated on the webpage as well at frequent time intervals. The certification will be awarded after the required levels of knowledge, skills, professionalism and attitude which will be assessed in the form of intermittent quizzes, assignments, case studies discussion and other modes of comprehensive online assessment tools.

### **Re- Examination:**

In case the participant is not able to pass the certification exam in first attempt/exam notification, he/she will have to re- register for the next scheduled examination by submitting re- registration form along with the re- registration fee of Rs. 1500/- (50 USD). However, the participants will be given sufficient flexibility in scheduling their “First” certification exam.

### **Course Deliverables:**

A comprehensive study material for all the modules in hard copies ensuring the needs of the audience. The sessions will be co-ordinated by industry experts and experts from academia who will be invited for conducting certain specialized session during the course. The accompanying training material is appropriately aligned with the current Industry’s expectations.

- ✓ Assignments for all the course modules for continuous evaluation and guidance.
- ✓ Interactive or online live sessions on all key areas of the course giving all flexibility to the participants.
- ✓ Online classes for all the modules will be conducted on the weekends. Moreover, a doubt clearing session will also be scheduled before the examination.
- ✓ All the efforts are made by GTU-GSP faculty members to make the entire course modules easily understandable.
- ✓ Assessment and evaluation for all the course modules in order to enhance the levels of competencies and skills of the participants leading towards the objective of application in the job.
- ✓ At the end of each course modules, the trainers shall obtain feedback from the participants using specially designed questionnaires.
- ✓ All learning and training delivery initiatives shall be conducted in English.

### **Placement Assistance & Corporate Relations:**

The Institute has partnered with many organizations for providing with placement assistance to its participants. Besides, GTU has a robust Industry Institute Interaction Cell (IIIC) comprised of senior level Human Resources professionals and Talent Acquisition experts which maintains close links with business and industry. This cell is continuously engaged in promoting the employability of our participants and encouraging the concerned Human Resources department and

Hiring Managers to recruit/hire our participants for their vacant positions. The efforts of our placement cell also include helping with professional resume writing & interview skills.

The GTU’s Industry Institute Interaction Cell (IIIC) actively recommends our students and training participants for various job requirements and specialized roles to Human Resource, Talent Acquisition as well as the heads of various departments in Pharmaceutical, Healthcare and Food industries on regular basis.

**Experts for the Course:** Several industry experts and experts from academia will be invited for conducting the course.

**Career opportunities:** Pharmaceutical product development forms the core of any pharmaceutical company and is responsible for ensuring the continuity of product pipeline for eventual commercialization. Person skilled in designing and developing newer products based on available information of innovator or commercial product will be an asset to any pharmaceutical formulation group. Such an individual could get job opportunities in pharmaceutical company as:

- **Formulation scientist**
- **Production executive**
- **R-D formulation executive**