# Shree H. N. Shukla Institute of Pharmaceutical Education & Research

**(Affiliated to Gujarat Technological University, Approved by PCI)**

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard, Amargadh – Bhichari, Rajkot. Mo. 9099063150, 9727753360


## M.Pharm
## PHARMACEUTICS
## SEMESTER: I

**Subject Name:** MODERN PHARMACEUTICS
**Subject Code:** MPH103T

**SCOPE:** Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

**OBJECTIVES:** Upon completion of the course, student shall be able to understand

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms.

**Teaching scheme and examination scheme:**

| Teaching Scheme | | | | Evaluation Scheme | | | |
|---|---|---|---|---|---|---|---|
| Theory | Tutorial | Practical | Total | Theory | | Practical | |
| | | | | External | Internal | External | Internal |
| 4 | 0 | 0 | 4 | 80 | 20 | 0 | 0 |

| Sr.No | Course content | Total Hrs |
|---|---|---|
| 1. | a. Preformation Concepts – Drug Excipient interactions – different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.<br>b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation | 10<br>10 |
| 2. | Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. | 10 |
| 3. | cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. | 10 |
| 4. | Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility | 10 |

| | | |
|---|---|---|
| 5. | Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors<br>– f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test | 10 |

**REFERENCES:**

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

**LEARNING OUTCOMES:**

| UNIT | LEARNING OUTCOME |
|---|---|
| **1** | Understand the general concept of Preformulation and optimization techniques. |
| **2** | Brief knowledge about the Validation process in pharmaceutical industries. |
| **3** | Appreciate the information of cGMP and TQM. |
| **4** | Knowledge regarding the Compression & Compaction process. |
| **5** | Understand the Consolidation parameters in defined form. |

**BOOK LIST:**

| Sr.no | Book name | Price (Rs.) |
|---|---|---|
| **1** | Theory and Practice of Industrial Pharmacy By Lachmann and Libermann. | 651/- |
| **2** | Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann. | 13,916/- |
| **3** | Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann. | 3,000/- |
| **4** | Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann. | 2,445/- |
| **5** | Modern Pharmaceutics; By Gillbert and S. Banker. | 10,431/- |
| **6** | Remington's Pharmaceutical Sciences. | 10,365/- |
| **7** | Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & | 49,984/- |

| | | |
|---|---|---|
| | A.H.Beckett. | |
| **8** | Physical Pharmacy; By Alfred martin. | 2,000/- |
| **9** | Bentley's Textbook of Pharmaceutics – by Rawlins. | 718/- |
| **10** | Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig. | 2,669/- |
| **11** | Quality Assurance Guide; By Organization of Pharmaceutical producers of India. | 1,499/- |
| **12** | Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi. | 2,536/- |
| **13** | Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash. | 1,02,981/- |
| **14** | Pharmaceutical Preformulations; By J.J. Wells. | 8,996/- |
| **15** | Applied production and operations management; By Evans, Anderson, Sweeney and Williams. | 528/- |
| **16** | Encyclopaedia of Pharmaceutical technology, Vol I – III. | 1,32,699/- |