MODERN PHARMACEUTICS
(MPH 103T)

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

- The elements of pre-formulation studies.
- The active pharmaceutical ingredients and generic drug product development.
- Industrial management and GMP considerations.
- Optimization techniques & pilot plant scale up techniques.
- Stability testing, sterilization process & packaging of dosage forms.

THEORY **60 Hrs**

1.	**(A)**. **Pre-formation 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. **(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 Hrs**
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 Hrs**
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 Hrs**
4.	**Compression and Compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, solubility.	**06 Hrs**
5.	**Study of Consolidation Parameters:** Diffusion parameters, dissolution parameters and pharmacokinetic parameters, Heckel plots, similarity factors – f2 and f1, Higuchi and Peppas plot, linearity Concept of significance, standard deviation, Chi square test, students T-test , ANOVA test.	**10 Hrs**

REFERNCES

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, by Sidney H. Willig. Second edition.
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.