PAPER III: PHARMACEUTICAL TECHNOLOGY AND VALIDATION

GOAL:

- To consistently achieve excellence in the field of drugs and pharmaceuticals with a thorough understanding of current global industrial requirements.

OBJECTIVES:

On completion of the course in Pharmaceutical technology and validation, the student must be able to -

- Gain a thorough understanding of all aspects related to development, manufacturing and evaluation of pharmaceuticals.
- Acquire adequate understanding of process design of pharmaceuticals.
- Understand the principles of validation in pharmaceutical industry

COURSE DESCRIPTION

THEORY **50hrs (2hrs/week)**

1. **Preformulation Studies**: Understanding concepts of physicochemical and biopharmaceutical characteristics in preformulation. Compatibility studies, protocol for product development. **(5hr)(20marks)**
2. **Dissolution Studies:** Biopharmaceutical Classification System (BCS) and its relevance to drug development, Factors affecting dissolution, Pharmacopoeial dissolution testing models, *In vitro – in vivo* correlation (IVIVC), Biowavers, Similarity factors.**(5hr)(20marks)**
3. **Drug Stability**: ICH guidelines for stability testing of drug substances and drug products. **(5hr)(15marks)**
4. Concepts of Pilot plant scale up and technology transfer, scale up and post approval changes (SUPAC) and bulk active chemicals post approval changes (BACPAC). **(5hr)(15marks)**
5. **Packaging of Pharmaceutical Products (Parenterals and Non - Parenterals**): Objectives, Types of packaging, Containers and closures, Quality control testing of primary and secondary packaging materials. Packaging of solid, semisolid and liquid dosage forms. Innovative packaging technologies. Product-package compatibility. (5**hr)(15marks)**
6. **Validation:** **(25hr)(55 marks)**
    - Introduction to calibration of instruments and its guidelines.
    - Introduction to Qualification and Validation,
    - Importance and scope of Validation.
    - Types of Validation,
    - Validation master plan.

- Process Validation of different dosage forms - solid, semisolids and parenterals
- Qualification of equipment: DQ, IQ, OQ and PQ(Validation of critical equipment - mixer, compression machine, fluidized bed dryer (FBD), filling equipment, sterilization tunnel.)
- Sterile equipment train Validation, Validation of HVAC systems including clean room concepts, air handling equipment and water supply systems (purified, distilled and water for injection).
- Cleaning Validation.
- Understanding of computer system validation (electronic records and digital signature-21 CFR Part 11) concept of firmware, Commercial off the Shelf (COTS) and GAMP 5

PRACTICALS **150hrs (6hrs/wk)**

1. Evaluation of marketed solid, semisolid and liquid dosage form as per Pharmacopeia. (3Expts)
2. Drug - drug and drug - excipients compatibility studies by TLC, FTIR and DSC. (3Expts)
3. Comparative dissolution study with interpretation of similarity factor f1 and f2 for drugs belonging to BCS class I and III drugs. (2Expts)
4. Determination of shelf life for a formulation based on ANCOVA. (Analysis of Covariance).
5. Preparation and execution of stability protocol for a pharmaceutical dosage form as per ICH guidelines.
6. Investigation of a case study based on Pilot plant scale up.
7. Quality control testing of primary and secondary packaging materials.
8. Evaluation of container closure integrity.
9. Determination of compatibility between drug substances and packaging material.
10. Qualification of Pharma Equipment (Tablet compression machine, Stability chamber, Mixer). (3Expts)
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester). (3Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESEMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the assessment marks for theory and practicals separately.

FINAL EXAMINATION (PRACTICAL)

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment	Viva-Voce	Total
20	35	25	20	100

REFERENCES:

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4. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio-Pharmaceuticals and Clinical Pharmokinetics, 3rd Edn, Lea &Febriger, Philadelphia.
6. Chow S-C. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.
7. Dressman JB, Kramer J. Pharmaceutical Dissolution Testing. Taylor & Francis; 2005.
8. Chilukuri DM, Sunkara G, Young D. Pharmaceutical Product Development: In Vitro-In Vivo Correlation. Informa Healthcare; 2007.
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17. Levin M. Pharmaceutical Process Scale-Up. CRC Press; 2001.
18. Piringer OG, Baner AL. Plastic Packaging: Interactions with Food and Pharmaceuticals. John Wiley & Sons; 2008.
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22. Dean DA, Evans R, Hall I. Pharmaceutical Packaging Technology. Taylor & Francis; 2000.
23. Calver G. What Is Packaging Design? Rotovision; 2007.
24. Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP and GLP Compliance. St. Lucie Press; 2002.
25. Wrigley GC. Facility Validation: Theory, Practice, and Tools. CRC Press; 2004.
26. Haider SI, Asif ES. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries. CRC Press; 2010.
27. Segalstad SH. International IT Regulations and Compliance: Quality Standards in the Pharmaceutical and Regulated Industries. John Wiley & Sons; 2008.
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29. Ira R. Berry and Robert A. Nash, Pharmaceutical process validation (Drugs and Pharmaceutical Series), Marcel Dekker Inc. New York.
30. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare; 2007.
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34. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press; 2000.
35. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press; 2000.

Websites:

1. http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html (ICH Stability guidelines Q1A-F)
2. http://apps.who.int/medicinedocs/documents/s19638en/s19638en.pdf(WHO Guidelines on packaging for pharmaceutical Products)
3. http://www.fda.gov/downloads/Drugs/Guidances/UCM070640.pdf (US FDA, Scale-Up and Post approval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation)
4. http://www.validation-online.net/pharmaceutical-validation.html (Sample validation documents)

Journals:

1. Indian Journal of Pharmaceutical Sciences.
2. Indian drugs
3. Journal of Validation Technology.
4. Pharmaceutical Engineering, International Society of Pharmaceutical Engineers.