# Gujarat Technological University

## M. Pharm.

Semester – III

**Paper code -930104**

# Validation and Product Development

## Subject of Specialization Paper – V (Quality Assurance)

## Theory

**(Four hours per week, 7 credits)**

1. **Introduction to Pharmaceutical Validation:**
   Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master Plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.
2. **Calibration Master plan**
   Validation of Equipment
   Concept of URS, DQ, IQ, OQ & PQ,
   Validation of following equipment
   - Dry Powder Mixers
   - Fluid Bed and Tray dryers.
   - Tablet Compression (Machine)
   - Dry Heat Sterilization/Tunnels
   - Autoclaves
   - Membrane filtration
   - Capsule filling machines.
   - Validation of Integrated lines by media fill test.
   - Validation of existing equipment.
3. **Vendor Certification**
4. **Utilities Validation**
   **a.** Validation of Pharmaceutical Water System & pure steam,
   **b.** Validation of HVAC system
   **c.** Validation of Compressed air
5. **Cleaning Validation:** Cleaning of Equipment, Cleaning of Facilities
6. **Analytical Method Validation**
   General principles of analytical method validation.
   Validation of following analytical Instruments
   - HPLC
   - Dissolution test apparatus
   - U.V./Visible spectrophotometers
7. **Process Validation**
   Prospective, concurrent, retrospective & revalidation, Process validation of following formulations
   - Coated tablets
   - Capsules
   - Ointment/Creams

- Liquid Orals

8. **Computer System Validation**
9. **Product development**
   **a.** In-process controls in manufacturing process design and development of:
   Tablets,
   Capsule
   Liquid orals
   Ophthalmic applications
   Aerosols
   Sterile parenteral
   **b.** Scale up operations, SUPAC guide line.

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## Practical

**(Six hours per week, 8 Credits)**

1. Validation of following equipment
   a. Autoclave b. Hot air oven c. Powder Mixer (Dry)
   **c.** Tablet Compression Machine
2. Pre-formulation studies of a model Drug.
3. Validation of analytical method (minimum four exercises).
4. Validation of a processing area.
5. Validation of at least two analytical instruments.
6. Cleaning validation of one equipment.

## Reference Books:


1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.