# C. U. SHAH UNIVERSITY

**Faculty**: - Pharmaceutical Sciences
**Department**: Pharmaceutical Chemistry & Pharmaceutical Analysis
**Discipline**: Quality Assurance
**Semester: III**
**Name of Subject**: Product development and Validation (Theory)
(Specialization-V)
**Subject Code**: 5PS03PDV2

**Teaching & Evaluation Scheme:-**

| Sr. No | Branch Code | Subject Code | Subject Name | Teaching hours/ week | | | | Credit | Evaluation Scheme/ Semester | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Theory | | | | Practical | | | |
| | | | | | | | | | Sessional Exam | | University Exam | | Internal | | University | Total |
| | | | | Th | Tu | Pr | Total | | Marks | Hrs | Marks | Hrs | Pr | TW | Pr | |
| 1 | 5 | 5PS03PDV2 | Product Development & Validation | 6 | - | 6 | 12 | 9 | 20<br>10 (CEC) | 1<br>-- | 70 | 3 | 20<br>10 (CEC) | - | 70 | 200 |

**OBJECTIVES:-**

- To train students about various aspect of calibration and validation
- To impart knowledge about official / non-official methods analytical method validation.
- To give wide exposure to students in the area validation.
- To give them training in carrying out some of these techniques in the laboratory

**PREREQUISITES:-**

- Basic knowledge of calibration and validation
- A B. Pharm. degree from any institution approved by AICTE or its equivalent

**Course Outline:-**

| Sr. No | Course Contents | Hours |
|---|---|---|
| 1 | **Introduction to Pharmaceutical Validation:**<br>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<br>Qualification of facilities. | 10 |
| 2 | **Calibration Master plan**<br>Validation of Equipment<br>Concept of URS, DQ, IQ, OQ & PQ,<br>Validation of following equipment<br>- Dry Powder Mixers<br>- Fluid Bed and Tray dryers.<br>- Tablet Compression (Machine)<br>- Dry Heat Sterilization/Tunnels<br>- Autoclaves<br>- Membrane filtration<br>- Capsule filling machines.<br>- Validation of Integrated lines by media fill test.<br>- Validation of existing equipment. | 25 |

| | | |
|---|---|---|
| 3 | **Vendor Certification** | 03 |
| 4 | **Utilities Validation**<br>**a.** Validation of Pharmaceutical Water System & pure steam,<br>**b.** Validation of HVAC system<br>**c.** Validation of Compressed air | 07 |
| 5 | **Cleaning Validation:** Cleaning of Equipment, Cleaning of Facilities | 08 |
| 6 | **Analytical Method Validation**<br>General principles of analytical method validation.<br>Validation of following analytical Instruments<br>- HPLC<br>- Dissolution test apparatus<br>- U.V./Visible spectrophotometers | 10 |
| 7 | **Process Validation**<br>Prospective, concurrent, retrospective & revalidation, Process validation of following<br>formulations<br>- Coated tablets<br>- Capsules<br>- Ointment/Creams<br>- Liquid Orals | 10 |
| 8 | Computer System Validation | 03 |
| 9 | Product development<br>a. In-process controls in manufacturing process design and development of:<br>Tablets,<br>Capsule<br>Liquid orals<br>Ophthalmic applications<br>Aerosols<br>Sterile Parenteral<br>b. Scale up operations, SUPAC guide line. | 14 |
| | Total | 90 |

# C. U. SHAH UNIVERSITY

**Faculty**: - Pharmaceutical Sciences
**Department**: Pharmaceutical Chemistry & Pharmaceutical Analysis
**Discipline**: Quality Assurance
**Semester: III**
**Name of Subject**: Product development and Validation (Practicals) (Specialization-V)
**Subject Code**: 5PS03PDV2

**Detailed Syllabus (Practical)**

1. Validation of following equipment
   a. Autoclave b. Hot air oven c. Powder Mixer (Dry)
   b. 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.

**Student Learning Outcomes**

The students are expected to

- Learn the Calibration of instrument
- Understand basic idea Analytical Method validation
- Understand concept Product development
- Understand Concept to prepare of Protocol for validation

**Instructional Methods and Pedagogy:**

- The faculty shall explain the lectures using black board,using Over Head Projector, Multimedia projector.

**Recommended 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.