

**Rajiv Gandhi University of Health Sciences, Karnataka**

**4th T Block Jayanagar, Bengaluru**

Curriculum delivery design of B. Pharm. course of Semester VII System

w.e.f Academic year 2020-21

**SEMESTER-VII**

**BP702T: INDUSTRIAL PHARMACY (Theory)**

**7th semester B. Pharm**

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market Objectives: Upon completion of the course, the student shall be able to: 1. Know the process of pilot plant and scale up of pharmaceutical dosage forms 2. Understand the process of technology transfer from lab scale to commercial batch 3. Know different laws and acts that regulate pharmaceutical industry in India and US 4. Understand the approval process and regulatory requirements for drug products

**45 Hours**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sl.**  **No**. | **Topic** | **Hours** | **Learning content distribution** | | | **Weightage**  **(Marks)** |
| **Must know** | **Desirable to know** | **Nice to know** |
| **Unit I** | Pilot plant scale up techniques: | 10 | General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, | Introduction to Platform technology | SUPAC guidelines | 19 |
| **Unit-II** | Technology development and transfer: | 10 | WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer | Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India -  APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation | confidentiality agreements, licensing, MoUs, legal issues | 24 |
| **Unit III** | Regulatory affairs:  Regulatory requirements for drug approval: | 04  06 | Introduction, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals Drug  Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator‘s Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Management of Clinical Studies | Historical overview of Regulatory Affairs,  Biostatistics in Pharmaceutical Product Development, | Data Presentation for FDA Submissions | 24 |
| **Unit-IV** | Quality management systems: | 08 | Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000,  GLP | Six Sigma concept | NABL | 14 |
| **Unit-V** | Indian Regulatory Requirements: | 07 | Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), | Regulatory requirements and approval procedures for New Drugs. | --- | 14 |

1. Blueprint of question paper, for each QP. This shows the weightage given to each chapter in the summative assessment. This improves the content validity by distributing the assessment of learners in the competencies that are represented by learning objectives under each chapter.

State the number of QPs for the subject.

The following template demonstrates how each QP Blueprint would look like:

1. Question paper layout to show which question number will represent which chapter (s)

**Long Essay: 2 × 10 = 20**

|  |  |
| --- | --- |
| 1 | Pilot plant scale up techniques: |
| 2 | Technology development and transfer: |
| 3 | Regulatory affairs: Regulatory requirements for drug approval: |

**Short Essays: 5 ×9 = 45**

|  |  |
| --- | --- |
| 4 | Pilot plant scale up techniques: |
| 5 | Technology development and transfer: |
| 6 | Regulatory affairs: Regulatory requirements for drug approval: |
| 7 | Quality management systems: |
| 8 | Indian Regulatory Requirements: |

**Short Answers: 2 × 10 = 20**

|  |  |
| --- | --- |
| 9 | Pilot plant scale up techniques: |
| 10 | Technology development and transfer: |
| 11 | Regulatory affairs: Regulatory requirements for drug approval: |
| 12 | Quality management systems: |
| 13 | Indian Regulatory Requirements: |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BLUE PRINT OF MODEL QUESTION PAPER  **BP 702 T: Industrial Pharmacy-II**  TIME: 3 HOURS MAX. MARKS: 75 | | | | | | | | |
| **Unit No** | **Hours** | **Must know** | | | **Desirable to know** | | | **Weightage of marks** |
| **LE**  **(10X3)** | **SE**  **(5X7)** | **SA**  **(2X5)** | **LE**  **(10X0)** | **SE**  **(5X2)** | **SA**  **(2X5)** |
| Unit-I | 10 | 1 | 1 | 1 | \_ |  | 1 | 19 |
| Unit-II | 10 | 1 | 2 | 1 | \_ | - | 1 | 24 |
| Unit-III | 10 | 1 | 2 | 1 | \_ |  | 1 | 24 |
| Unit-IV | 08 | - | 1 | 1 | \_ | 1 | 1 | 14 |
| Unit-V | 07 | - | 1 | 1 | \_ | 1 | 1 | 14 |
| **Total** | **45** | **30** | **35** | **10** | **-** | **10** | **10** | **95** |
|  |  | **75** | | | **20** | | | **95** |