

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)
SEMESTER	2
COURSE TITLE	PHARMACEUTICAL MANUFACTURING TECHNOLOGY
COURSE CODE	13MQ0204
COURSE CREDITS	4

Objective:

- 1 This course is designed to impart knowledge and skills necessary to train the students in industrial activities during Pharmaceutical Manufacturing.

Course Outcomes: After completion of this course, student will be able to:

- 1 At the completion of this course, it is expected that students will be able to understand,-- The common practice in the pharmaceutical industry developments, plant layout, and production planning
- 2 At the completion of this course, it is expected that students will be able to understand,-- Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology, and packaging technology.
- 3 At the completion of this course, it is expected that students will be able to understand,-- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

Pre-requisite of course: Nil

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	Unit-1 Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing., Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout., Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, and production control.	12

Contents : Unit	Topics	Contact Hours
2	<p>Unit-2</p> <p>Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume)., Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance., Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS)., Lyophilization technology: Principles, process, equipment.</p>	12
3	<p>Unit-3</p> <p>Non-sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft)., Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, , Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered, Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.</p>	12
4	<p>Unit-4</p> <p>Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.</p>	12

Contents : Unit	Topics	Contact Hours
5	Unit-5 Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	12
Total Hours		60

Textbook :

- 1 The Theory and practice of industrial pharmacy, third ed, Lachman L, Liberman HA, Kanig JL. , Varghese Publishers, Mumbai , 1991
- 2 Martin's physical pharmacy and pharmaceutical sciences, 5 ed., Sinko PJ, B.I. Publications Pvt. Ltd. , 2006
- 3 Pharmaceutical dosage forms: tablets Vol. I-III, 2ed., , Lieberman HA, Lachman L, Schwartz JB. , CBS Publishers & distributors, New Delhi, , 2005
- 4 Modern Pharmaceutics, 4 ed., Banker GS, Rhodes CT. , Marcel Dekker Inc, New York, , 2005
- 5 Indian Pharmacopoeia. , Controller of Puopoeia Commissionblication, Indian PharmacController of Publication, 1996
- 6 United States Pharmacopoeia, United States Pharmacopeial Convention, Inc, USA, , United States Pharmacopeial Convention, Inc, USA, , 2003
- 7 British Pharmacopoeia, BPC, British Pharmacopoeia Commission Office, London, , 2008

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
20.00	25.00	25.00	15.00	10.00	5.00

Instructional Method:

- 1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.

Instructional Method:

- 2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.
- 3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.