Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard, Amargadh – Bhichari, Rajkot. Mo. 9099063150, 9727753360

M.Pharm
PHARMACEUTICAL QUALITY ASSURANCE
SEMESTER: II

Subject Name: PHARMACEUTICAL MANUFACTURING TECHNOLOGY
Subject Code: MQA204T

Scope: This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives: Upon completion of this course the student should be able to

1. The common practice in the pharmaceutical industry developments, plant layout and production planning
2. Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	0	0	4	80	20	0	0

Sr No	Course Contents	Total Hrs
1	Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing. Plant layout: Factors influencing, Special provisions, Storage spacerequirements,sterile and asepticarea layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control	12
2	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	12
3	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	12

	&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	
4	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	12
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

REFERENCES:

1. Lachman L,Lieberman HA,Kanig JL. The theory and practice of industrial rd pharmacy, 3 ed., Varghese Publishers, Mumbai 1991
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed.,B.I.PublicationsPvt. Ltd,Noida,2006
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosageforms: nd tabletsVol.I-III,2 ed.,CBS Publishers & distributors ,New Delhi, 2005
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York,2005
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai
6. Indian Pharmacopoeia. Controller ofPublication.Delhi,1996
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London,2008
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc,USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor&Francis,1st Edition.UK
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009.Informa Healthcare USA Inc. New York
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey andSons,NewJersey,2008

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOME
1	Learning about the concept of Pharmaceutical industry developments.
2	Knowledge about the Aseptic process technology.
3	Appreciate the Non sterile manufacturing process technology.
4	Understand the Containers and closures for pharmaceuticals.
5	Knowledge about Quality by design (QbD) and process analytical technology (PAT).

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	Lachman L,Lieberman HA,Kanig JL. The theory and practice of industrial rd pharmacy, 3 ed., Varghese Publishers, Mumbai 1991	2734/-
2	Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed.,B.I.PublicationsPvt. Ltd,Noida,2006	2,000/-
3	Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosageforms: nd tabletsVol.I-III,2 ed.,CBS Publishers & distributors ,New Delhi, 2005	651/-
4	Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York,2005	1,007/-
5	Indian Pharmacopoeia. Controller ofPublication.Delhi,1996	26,065/-
6	British Pharmacopoeia. British Pharmacopoeia Commission Office, London,2008.	81,794/-
7	United States Pharmacopoeia. United States Pharmacopeial Convention, Inc,USA, 2003.	87,115/-
8	Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor&Francis,1st Edition.UK.	28,989/-
9	Edward J Bauer. Pharmaceutical Packaging Handbook. 2009.Informa Healthcare USA Inc. New York.	11,120/-
10	Shaybe Cox Gad. Pharmaceutical ManufacturinHandbook. John Willey andSons,NewJersey,2008.	16,597/-