Study Scheme & Syllabus of Post Graduate Diploma in Pharmaceutical Packaging

Batch 2018 onwards

By

Board of Study Pharmacy

Department of Academics

IK Gujral Punjab Technical University

First Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
PGDPP 101-18	Core Theory-I	Fundamentals of Packaging	4	-	-	40	60	100	4
PGDPP 102-18	Core Theory-II	Advances in Packaging-I	4	-	-	40	60	100	4
PGDPP 103-18	Core Theory-III	Quality Control of Packaging Material-I	4	-	-	40	60	100	4
PGDMAT 104-18	Core Theory-IV	Modern Analytical Techniques	4	-		40	60	100	4
PGDPP 105-18	Core Practical-I	Packaging Technology &Quality Control Lab-I	-	-	4	60	40	100	2
PGDMAT106-18	Core Practical-II	Modern Analytical Techniques Lab		-	4	60	40	100	2
PGDPP 107-18	Skill Enhancement	Seminar/Journal Club	4	-	-	100	-	100	4
PGDPP 108-18	Skill Enhancement	Project-I	-	-	4	-	100	100	2
		Total	**20**		**12**	**380**	**420**	**800**	**26**

Second Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
PGDPP201-18	Core Theory-V	Advances in Packaging-II	4	-	-	40	60	100	4
PGDPP202-18	Core Theory-VI	Quality Control of Packaging Material-II	4	-	-	40	60	100	4
PGDIPR203-18	Core Theory-VII	Intellectual Property Rights& Documentation	4	-	-	40	60	100	4
PGDPP204-18	Core Practical-III	Packaging Technology & Quality Control Lab-II	-	-	4	60	40	100	2
PGDPP205-18	Skill Enhancement	Seminar/Journal Club	4	-	-	100	-	100	4
PGDPP206-18	Skill Enhancement	Industrial Training*	-	-	-	50	50	100	4
PGDPP207-18	Skill Enhancement	Project-II	-	-	12	-	200	200	6
		Total	**16**		**16**	**330**	**470**	**800**	**28**

*Industrial Training of two weeks duration will be undertaken after 1st semester and before commencement of 2nd semester

1st SEMESTER

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDPP 101-18	Fundamentals of Packaging	4	-	-	40	60	1.5	3	4

Scope: This course is designed to impart advance knowledge on pharmaceutical product packaging development.

Course Outcomes: Upon completion of the course, the student shall be able to

1. Know the use of different polymers in packaging.
2. Understand the process of packaging of dosage forms.

1. **Introduction:** Plastics and Polymers Raw Materials of Plastics, Types of Plastics, Resin Identification Code, Plastics and Packaging, Testing of Plastic Containers. **03 Hrs**

2. **Introduction**: Natural and Synthetic Rubber Types of Closures, Classification of Contemporary Closures by their Utility, Special Purpose Closures, Closure Functions, Closure Materials, Types of Plastic Closures, Sealing Systems, Liners, Closure Liner Functions, Classification of Liners, Selection of Lining Material, Options for Closure Liners, Innerseals, Linerless Closures, Types of Tapes, Strapping Materials, Evaluating Closure Liners, Standard Liners, Tacseal, Solutions, Liner Description, Liner Designations. **09Hrs**

3. **Introduction:**Selection of Glass as Packaging Materials for the Pharmaceutical Products, Advantages and Disadvantages of Glass Containers,Properties of Glass, Production of Glass, Types of Glasses, Manufacturing of Glass Containers, Testing Of Glass Containers. **06 Hrs**

4. **Plastic Packaging Materials:** Containers and Closures Introduction, Methods of Preparation, Classification of Materials, Drug-Plastic Considerations, Selection of Proper Materials, Drug Plastic Considerations, Selection of Proper Materials. **06 Hrs**

5. **Liquid Formulation Packaging:**Various Containers/Closures Employed for Liquid Formulations. Machinery Employed for Liquid Filling–Constant Level, Volumetric, Gravimetric Etc. Evaluation of Liquid Formulation Packages. **04Hrs**

6. **Semi-Solid Packaging:**VariousTypes Of Containers/Packages Used for Semisolid Products, Filling and Sealing Machinery (Including Collapsible Tube Filling and Sealing Machine) Merits and Limitations of Various Packages, Evaluation of Semi-Solid Product Package. **05Hrs**

7. **Sterile Product Packaging:**General Principles of Packaging of Sterile Products. Various Types of Containers Used for Sterile Products Including Small Volume and Large Volume Parenterals. Types of Closures Used for The Sterile Products. Sterile Product

Filling and Sealing Machinery I.E. Ampoule Filling and Sealing Machine,Limitations and Merits of Various Packages. Evaluation of the Sterile Product Packages. **06 Hrs**

8. **Labeling**Typeof Labels (Including Bar Code, RF, Structured Program, In Mould and Decorative Labeling), Legal Requirements of Labeling, Packaging Inserts and Outserts. Adhesives and Machinery Employed for Labeling, Concept of Paperless Labeling.**06 Hrs**

Recommended Books (Latest Edition)

1. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA.
2. Wilmer A. Jenkins, Kenton R. Osborn. Packaging Drugs and Pharmaceuticals.
3. Salvatore J. Turco, Sterile Dosage Forms: Their Preparation and Clinical Application.
4. Remington: The Science and Practice of Pharmacy.
5. Michael E. Aulton, Kevin Tylor (Ed.). Aulton's Pharmaceutics: The Design and Manufacture of Medicine.
6. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
7. Leon Lachman; Lieberman Herbert A.Kanig, Joseph L.The Theory and Practice of Industrial Pharmacy.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDPP 102-18	Advancesin Packaging-I	4	-	-	40	60	1.5	3	4

Scope: This subject is designed to impart knowledge and skills of pharmaceutical product packaging and their applications in pharmaceuticals.

Course Outcomes: Upon completion of the course student shall be able to

1. Understand the basic concepts of fundamental packaging and their significance.
2. To understand the concepts of packaging materials of various dosage forms.
3. Understand current trends in pharmaceutical packaging.

1. **Introduction:** FDA Definitions**,** Purpose of Packaging, Selection of the Ideal Package, Classification of Packaging and Various Types of Inner and Outer Packages, Hazards Encountered by the Package. **06 Hrs**
2. **Packaging Materials:** Packaging Characteristics, Advantages, Economics and Limitations of Various Packaging Materials, Approach to Package Design, New Trends in the Pharmaceutical Packaging, Packaging Recycling Symbols. **07 Hrs**
3. **Strip Packing:** Significance of Strip Packing, Advantages, Economics and Limitations of Strip Packing, Strip Packing Machinery, Films Employed in Strip Packing (Including Composites and Laminates) and Evaluation of Films and Strips Packs. **07 Hrs**
4. **Blister Packaging:** Blister Packing Materials, Significance ofBlister Packing, Advantages, Economics and Limitation of Blister Packing, Blister Packing Machinery, Various Types of Blister Packages, and Evaluation of Blister Package. **08 Hrs**
5. **Pouch Packaging:** Economics and Limitations of Pouch Packing, Pouch Packing Machinery, Spectrum of Applications and Evaluation of Pouch Packing. **05 Hrs**
6. **Metal Packaging**: Oriented and Non-Oriented, Film and Laminate, Aluminium and Aluminium Foil, Collapsible Tubes, Tin, Stainless Steel. **05 Hrs**
7. Child Resistant Package andTamper Evident Packaging. **03 Hrs**
8. **Current Trend In Future:** Ink Technology, RFID (Radio Frequency Identification), Holographic Materials And Eco-Friendly Pharmaceutical Packaging **04 Hrs**

Recommended Books (Latest Edition)

1. AI Brody & K S Marsh, "The Wiley Encyclopedia of Packaging Technology", John Wiley & Sons, New York

2. Leon Lachman, H A Liberman and J L Kanig, "The Theory and Practice of Industrial Pharmacy", Lea &Febiger, Philadelphia
3. Sanju Nanda, Rakesh Pahwa and Arun Nanda. "Pharmaceutical Packaging Technology, New Age Publications, New Delhi.
4. T C KacChesney, "Packaging of Cosmetics and Toiletries", Newness-Butterworth, London
5. "Remington' Pharmaceutical Sciences", Mack Publishing Co., P.A
6. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical Packaging Technology, Tylor and Francis.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDPP 103-18	Quality Control of Packaging Material-I	4	-	-	40	60	1.5	3	4

Scope: This course deals with the various aspects of quality control aspects of packaging in pharmaceutical industries. It deals with the important aspects like ICH guidelines, QC tests, documentation, and quality certifications.

Course Outcomes: Upon completion of the course, the student shall be able to

1. Understand the various quality control tests for packaging material.
2. Importance of documentation.
3. Understand the scope of quality certifications applicable to pharmaceutical industries

1. **Guidelines on Packaging for Pharmaceutical Products:** Quality Assurance Aspects of Packaging, General Considerations, Quality Control, Sampling, Testing Programmer,Inspection and Audit, Rules, Audits of Suppliers. **06Hrs**

2. **Quality Specifications:** Requirements in the International Pharmacopoeia, Packaging Materials, Requirements for Dosage Form Containers. **04Hrs**

3. **Defects in Packages:** Introduction, Defects in Packaging Material, Protection from the Environment, Packaging Waste and Waste Policies. **04Hrs**

4. **Package Testing And Testing of Containers &Closures:** Introduction, Testing of Containers and Closures. **05Hrs**

5. **Sterilization of Packaging Materials:** Introduction, Pharmaceutical Importance of Sterilization,Classification of Sterilization Methods,Factor Affecting Sterilization, Sterilization of PackagingMaterials, Tests for Sterility, Incubation and Examination of Sterility Tests, Interpretation of TheTest Results, Evaluation of Sterilization Method, Process of Microbial Destruction, Evaluation. **10Hrs**

6. **In Process Monitoring of Sterilization:** Procedures Packaging of Parenterals, Ophthalmic, Packaging, Packaging Components, Inspection of Filled Injectable Products, Storage and Labeling, Storage and Packaging of Aerosols. **10Hrs**

7. **Stability Of Packages:** Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines. **06 Hrs**

Recommended Books (Latest Edition)

1. Leon Lachman, H A Liberman and J L Kanig, "The Theory and Practice of Industrial Pharmacy", Lea &Febiger, Philadelphia.
2. Sanju Nanda, RakeshPahwa and Arun Nanda. "Pharmaceutical Packaging Technology, New Age Publications, New Delhi.
3. T C KacChesney, "Packaging of Cosmetics and Toiletries", Newness-Butterworth, London.
4. "Remington' Pharmaceutical Sciences", Mack Publishing Co., P.A
5. Michael E. Aulton, Kevin Tylor (Ed.). Aulton's Pharmaceutics: The design and Manufacture of Medicine.
6. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
7. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The Theory and Practice of Industrial Pharmacy.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDMAT 104-18	Modern Analytical Techniques	4	-	-	40	60	1.5	3	4

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Course Outcomes: Upon completion of the course, the student shall be able to know

1. Analysis of drugs using various analytical instruments.
2. Understand the chromatographic separation and analysis of drugs.
3. Understand the advanced instruments used and its applications in drug analysis.

Module 01 **08Hrs**

a. Pharmaceutical analysis-Definition and scope , Different techniques of analysis , Methods of expressing concentration , Primary and secondary standards, Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate
b. Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.
c. Calibration and validation-as per ICH and USFDA guidelines Calibration of following Instruments Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

Module 02 **11Hrs**

a. UV Visible spectroscopy: Introduction, Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications
b. IR spectroscopy: Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Module 03 **11Hrs**

a. Nuclear Magnetic Resonance spectroscopy: Principles of ^{1}H-NMR and ^{13}C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications
b. Mass Spectrometry: Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

Module 04 **15Hrs**

a. Introduction to chromatography
b. Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.
c. Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications
d. Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications
e. High performance liquid chromatography (HPLC) - Introduction, theory, instrumentation, advantages and applications.

Recommended Books

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic Spectroscopy by Y.R Sharma
3. Vogel's Text Book of Quantitative Chemical Analysis by A.I. Vogel
4. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
5. Organic Spectroscopy by William Kemp
6. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
7. Spectrophotometric identification of Organic Compounds by Silverstein
8. Text book of Pharmaceutical Analysis Vol, II and III by Arora and Arora S. Vikas and company Jalandhar

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDPP 105-18	Packaging Technology & Quality Control Lab-I	-	-	4	60	40	6	6	2

1. Experiment based on Glass, Metal, Fibreboard
2. Permeability Shelf Life of Container
3. Experiment based On Plastics
4. Experiment based on Sealing, Leak Test, Coating Laminates
5. Experiment based on Material Container inTraction Test.
6. Experiment based on Sterility
7. Experiment based on Testing of Cellulose& Paper Material

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDMAT 106-18	Modern Analytical Techniques Lab	-	-	4	60	40	6	6	2

1. Measurement of absorption maxima of some standard Pharmacopoeial drugs
2. Separation of compounds of a mixture by TLC
3. Demonstration experiment on HPLC
4. Demonstration experiment on GC
5. Assay of Pharmacopoeial drugs (minimum 5)

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PGDPP 108-18	Project-I	-	-	4	100	-	1	-	2

The candidate shall prepare a report on a topic of recent development assigned by the mentor. The candidate shall also give a presentation to be evaluated by both internal and external examiners.

Evaluation Scheme

Report	:	25 marks
Presentation	:	25 marks
Viva-Voce	:	50 marks