

M. PHARM.
PHARMACEUTICAL MARKETING AND MANAGEMENT

GOAL:

To make the candidate an innovative, skillful and effective professional, who can raise industry standards, bring profits and name to the nation.

OBJECTIVE:

Upon completion of the course the candidate:

- Will gain specialized knowledge in marketing of pharmaceutical products.
- Will become a skilled profit making marketer with adequate knowledge of financial management.
- Will be a skilled leader in a pharmaceutical company.
- Will be able to raise standards of the pharmaceutical industry in the current global scenario.

TITLE OF PAPERS:

PAPER I : Pharmacological Basis of Disease Management	(T: 3hrs/wk, P: 6 hrs/wk)
PAPER II : Pharmaceutical Marketing	(T: 2hrs/wk, P: 6 hrs/wk)
PAPER III : Pharmaceutical Management	(T: 2hrs/wk, P: 6 hrs/wk)
PAPER IV : Production Management and Regulatory Affairs	(T: 2hrs/wk, P: 6 hrs/wk)

PAPER I: PHARMACOLOGICAL BASIS OF DISEASE MANAGEMENT

GOAL: To help the students to identify and understand the need gap in disease management.

OBJECTIVES: Upon completion of the course the candidate will be able to:

- Discuss the standard guidelines of top therapy areas
- Acquire skills to analyze the need gap in disease management
- Identify the USP of drugs
- Develop the ability to impart / exchange scientific knowledge with Sales personnel, Doctors and Higher Management.

COURSE DESCRIPTION

THEORY

75 Hours (3Hrs/ wk.)

1. ICD - CURRENT GUIDELINES ON DISEASES (1hr.)
2. BASIC PHARMACOLOGY
 - I. Introduction.
 - II. Drug receptor binding, ion channels and G-protein coupled receptors, secondary messenger systems (5hrs.)
 - III. Basics of pharmacodynamics and pharmacokinetics and drug bio-transformation. (5 hrs.)
 - IV. Clinical interpretation of drug concentration. (2 hrs.)
 - V. Basic and clinical evaluation of new drugs. (2 hrs.)
3. Key therapy areas to be focused with respect to the guidelines, class of drugs, and the differentiating points between the inter class and intra class of drugs.
 - I. INFECTIOUS DISEASES (6hrs.)
 - II. NEOPLASTIC DISEASES (6 hrs.)
 - III. BLOOD DISORDERS. (2 hrs.)
 - a. ANEMIA
 - b. COAGULATION DISORDERS
 - IV. METABOLIC DISORDERS. (4hrs.)
 - a. DIABETES MELLITUS
 - b. HYPERLIPIDEMIA
 - V. MENTAL AND BEHAVIOURAL DISORDERS. (8 hrs.)
 - a. ANXIETY
 - b. SCHIZOPHRENIA
 - c. AFFECTIVE DISORDERS
 - d. DEMENTIA
 - e. PARKINSONISM

VI.	CARDIAC DISEASES.	(6hrs.)
	a. HYPERTENSION	
	b. ISCHEMIC HEART DISEASES	
	c. CONGESTIVE CARDIAC FAILURE	
VII.	GASTROINTESTINAL DISORDERS.	(4 hrs.)
	a. PEPTIC ULCER	
	b. GERD	
VIII.	RESPIRATORY AND ALLERGIC DISEASES	(4 hrs.)
	a. ASTHMA	
	b. COPD	
IX.	GENITOURINARY DISEASES	(6 hrs.)
	a. KIDNEY DISEASES	
	b. UROLITHIASIS	
	c. GENITAL DISEASES	
X.	SKIN DISEASES	(4hrs.)
	a. BULLOUS DISORDERS	
	b. DERMATITIS AND ECZEMA	
	c. URTICARIA AND ERYTHEMA	
XI.	MUSCULOSKELETAL SYSTEM DISEASES.	(6 Hrs.)
	a. OSTEO ARTHRITIS	
	b. GOUT	
	c. SPONDYLITIS	
	d. OSTEOPOROSIS	
XII.	MISCELLANEOUS:	(4 Hrs.)
	a. GLAUCOMA	
	b. OTITIS	

PRACTICALS:

150 hrs. (6 Hrs/wk.)

1. Identification of USP to switch over from one product to another.
 - a. Data collection.
 - b. Write up.
 - c. Visual Aid.
 - d. Training Slides
 - e. Medico Marketing Aids
2. Current Guidelines Discussion of Top Therapy Areas.
3. Handling Scientific Objections: Doctor Query Management/ Case Situation.

TEXT BOOKS:

1. Pharmacology 3rd edition, Rang. H. P., Dale M.M. And Ritter J.M 1995 Churchill Living Stone.
2. Basic and Clinical Pharmacology, 5th edition, Katzung B.G (editor), 1992 Mcgraw Hill.
3. Oxford Handbook of Clinical Medicine, 5th revised edition, Longmore M, Hope R.A , Ian Wilkinson I, Torok E. Oxford University Press Inc, 2001.
4. Davidson's Principles and Practice of Medicine, 21 edition, Colledge N.R, Walker B.R, H. Ralston S.H, Churchill Livingstone, 2010.

REFERENCE BOOKS:

1. Goodman and Gilman's the Pharmacologicals Basis of Therapeutics, 10th edition, Hardman J.D. and Limbird L.E (Editor –in Chief), 2001 Mcgraw- Hill (Medical Publishing Division)
2. Clinical Pharmacy and Therapeutics, 3rd edition, Walker R, Edwards C.R.W, Churchill Livingstone, 2002.
3. Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 9th edition, Bonow, R.O, Douglas L., Zipes D.P, Libby P., 2011, Saunders.
4. Joslin's Diabetes Mellitus, 14th Edition, Kahn C.R, Weir G , King G, Jacobson A, Smith R, Moses A, (editors) Lippincott Williams & Wilkins, 2004
5. Cancer: Principles and Practice of Oncology , 9th north American edition, Vita d, Hellman, Rosenberg, Lippincott Williams & Wilkins, 2011.

WEB REFERENCES:

1. <http://www.idsociety.org> (IDSA)
2. <http://www.heart.org> (AHA)
3. <http://www.diabetes.org> (Diabetes association)
4. <http://www.escardio.org> (ESC)
5. <http://emedicine.medscape.com>
6. <http://www.hon.ch>(HONCODE SITE)
7. <http://apps.who.int/classifications/icd10/browse/2010/en#/XIII>(ICD GUIDELINES)

JOURNALS:

1. JAMA (Journal Of American Medical Association)
2. NEJM (New England Journal Of Medicine)
3. BMJ (British Medical Journal)
4. LANCET
5. JAPI (Journal Of Association Of Physician Of India)

SCHEME OF ANNUAL PRACTICAL EXAMINATION:

- | | |
|---|------------------|
| 1. Synopsis | 20 Marks |
| 2. Major Experiment: | 35 Marks |
| Switching Doctors from X to Y drug based on USP's of the given drugs. | |
| 3. Discussion on the guidelines of the given therapy class. | 25 Marks |
| 4. Viva voce | 20 Marks |
| TOTAL | 100 Marks |

PAPER II. PHARMACEUTICAL MARKETING

GOAL: To prepare the candidate to acquire sufficient knowledge in marketing management principles so that he/ she can handle product management, field management, training the field force, market research, industrial business, institutional business and international business, effectively, efficiently and profitably.

OBJECTIVES: Upon completion of course the candidate shall

- **Gain knowledge in Product Management of Pharmaceutical Products**
- **Gain knowledge of Marketing Management and Sales Management**
- **Acquire skills in Brand Planning**
- **Acquire skills to Launch a Product**
- **Raise Product Management standards**

COURSE DESCRIPTION

THEORY

50 Hours (2 Hrs/wk)

1. Marketing Concepts

(04 Hours)

- a. Global Pharmaceutical Industry scenario
- b. Indian Pharmaceutical Industry scenario
- c. Specificities of Pharmaceutical Marketing
- d. Role of Marketing in today's organization
- e. Identifying and classifying markets.
- f. Tasks of Marketing and Planning

2. Understanding Consumer Behavior

(03 Hours)

- a. Differentiating between consumer and customer in Pharmaceutical Marketing
- b. Consumer behavior models
- c. Physician's prescribing habits
- d. Rational and emotional decision making

3. Market Segmentation, Targeting and Positioning

(08 Hours)

i. Market Segmentation

- a. Definition and approaches to segmenting a market
- b. Bases for segmenting a pharmaceutical market
- c. Advantages and drawbacks of segmentation

ii. Market Targeting

- a. Evaluation of Market Segments
- b. Target Market Selection

iii. Product Positioning

- a. Definition, types of positioning
- b. Positioning Strategies

4. Product

(07 Hours)

- a) Concept of Product Management
- b) Understanding the Product Manager's role
- c) Understanding the Product, and its market
- d) SWOT analysis, Porter's Five Forces analysis, BCG Matrix(Portfolio analysis), Ansoff's Matrix
- e) Product financial justification (Profit and Loss, cash flow analysis)
- f) New Product Launch Strategy
- g) Product Life Cycle Management for Pharmaceutical Products
- h) Branding and Brand Management.

5. Place

(02 Hours)

- a) Study of Distribution Channels in Pharmaceutical industry
- b) Role of Carrying and Forwarding agents, Wholesalers, Stockists and Retailers

6. Price

(02 Hours)

- a) Pricing strategies
- b) Bases of Pricing
- c) Drug Price Control Order
- d) National Drug Policy

7. Promotion

(06 Hours)

- a) Verbal and Non verbal communication
- b) Elements of Promotion mix
- c) Medico Marketing aids
 - Written aids- Leave behind literature, visual aids
 - Digital aids- Slide kits, Flash presentations
 - Event Management- Continuing Medical Education, Key opinion Leaders(International and National)
- d) Promotional budget

8. Competitor Analysis

(02 Hours)

- a) Competitive Intelligence
- b) Competitive Advantages

9. Marketing Strategies

(04 Hours)

- a) Understanding Strategy, Tactics and Objectives
- b) Types of Marketing Strategies
- c) Product Strategies
- d) Promotional Strategies
- e) Sales Strategies
- f) Distribution Strategies
- g) Pricing Strategies
- h) Differentiation Strategies

10. Marketing Research

(03 Hours)

- a) Primary and Secondary Research
- b) Sampling Techniques-Probability and Non Probability
- c) Questionnaire Design
- d) Data Collection
- e) Data Analysis

11. International Marketing**(03 Hours)**

- a) Factors to be considered in International Marketing of Pharmaceutical Products
- b) Understanding the impact of the following factors in International Marketing:
 - Political Environment
 - Economical Environment
 - Social Environment
 - Technological Environment
 - Regulatory Environment
 - Cultural Environment
- c) Study of Marketing Mix elements and Market Entry strategies for regulated and semi-regulated markets.
- d) Foreign Trade Policy (EXIM Policy)

12. Pharmaceutical Marketing Codes**(02 Hours)**

- a. OPPI Code
- b. Uniform Codes of Pharmaceutical Marketing Practice

13. Field Personnel Training**(02 Hours)**

- a. Communication on product.
- b. How, when why, what to communicate?

14. Industrial Marketing**(02 Hours)**

- a. Comparison between Consumer Marketing and Industrial Marketing
- b. Marketing Mix Decisions with reference to Industrial Products.

PRACTICALS

150 Hours (6 Hrs/wk)

- i. Case studies (15), group discussions (10) and 2 role plays.
- ii. Preparation and presentation of campaigns.
- iii. Market survey and short term project
- iv. News capsule
- v. Preparation and submission of marketing plan for a given Molecule/Product.

SCHEME OF ANNUAL PRACTICAL EXAMINATION:

1. Synopsis	20 marks
2. Case study	15 marks
3. Group discussion	15 marks
4. Brand Plan for given Drug / Product	30 marks
5. Viva voce	20 marks

TOTAL

100 marks

Text Books :

1. Marketing Management by Philip Kotler, Kevin Lane Keller, Abraham Koshy, Mithileshwar Jha (Latest Edition), Published by Prentice-Hall Pvt Ltd.
2. A Framework for Marketing Management by Philip Kotler, Kevin Lane Keller (Latest Edition), Published by Prentice-Hall Pvt. Ltd.
3. Principles Of Marketing by Philip Kotler, Gary Armstrong (Latest Edition), Published by Prentice-Hall Pvt. Ltd.
4. Pharmaceutical Marketing In India: Concepts, Strategy, Cases by Subba Rao Chaganti (Latest Edition), Published by Pharma Book Syndicate.
5. Principles of Pharmaceutical Marketing by Mickey C Smith (Latest Edition), Published by CBS Publishers & Distributors.
6. Pharmaceutical Marketing in 21st Century by Mickey C Smith (Latest Edition), Published by Viva Books Pvt. Ltd. ,New Delhi-2.

Reference Books :

1. Essentials of Human Resource Management and Industrial Relations by Subbarao.P (Latest Edition), Published by Himalaya Publishing House.
2. Marketing Research : An Applied Orientation by Naresh K Malhotra (Latest Edition), Published by Prentice-Hall Pvt Ltd.
3. Pharmaceutical Marketing : A Practical Guide by Dimitris Dogramatz (Latest Edition), Published by CRS Press.
4. Marketing Warfare : How to use Military Principles to develop Marketing Strategies by Al Ries, Jack Trout (Latest Edition), Published by Listen USA.
5. Positioning : The Battle for your Mind by Al Ries, Jack Trout, Philip Kotler (Latest Edition), Published by McGraw-Hill.
6. Marketing Planning for the Pharmaceutical Industry by John Lindstone, Janice Maclellan (Latest Edition), Published by Gower Pub Co..
7. Revitalizing the Pharmaceutical Business : Innovative Marketing Approaches by R.B. Smarta (Latest Edition), Published by Response Books (Sage Publications).
8. Brand Positioning : Strategies for Competitive Advantage by Subroto Sengupta (Latest Edition), Published by Tata McGraw-Hill.

Journals:

1. Pharma Pulse
2. IDMA Bulletin
3. Harvard Business Review
4. 4Ps
5. Pharma Executive
6. Indian Journal of Marketing

PAPER III. PHARMACEUTICAL MANAGEMENT

GOAL: To prepare candidates in General Management and inculcate the Managerial Skills.

OBJECTIVES: At the end of the course, the candidate will :

- Gain knowledge in General Management
- Learn about Organizational Behavior, HRM, Financial Management, Operations Management and Quality Management.
- Gain skills in Distribution Management.
- Learn about Corporate Governance, Ethics, Shareholders value creation and Corporate Social Responsibility (CSR)
- Bring awareness about Quality and Productivity Tools: Enterprise Resource Planning (ERP), Material Resource Planning (MRP), Total Quality Management (TQM) and Kaizen.

COURSE DESCRIPTION

THEORY

50 Hours (2Hrs/wk)

1. Introduction to Management Aspects

(05 Hours)

- Concept, Nature and purpose of Management.
- Professional Managers- Tasks, Responsibilities and Skills needed.
- Leadership styles.
- Decision Making- Types, Procedures, Evaluation and Selection of Alternatives.
- Decision Making under various situations.
- Types of organization structure and map : Pharmaceutical Company as a model.
- Organizational Culture.

2. Organizational Behavior

(07 Hours)

- Meaning.
- Foundation of Organizational Behavior.
- Perceptions, Motivation, Emotions.
- Foundation of Group Behavior.
- Communication skills.
- Conflict Management.
- Foundation of Organizational Structures.

3. Human Resource Management (HRM)

(06 Hours)

- Human resource planning.
- Recruitment and Interviewing.
- Human skills evaluation through various instruments : Job Description, Job Evaluation, Role Clarity.
- Performance Appraisal Methods, Rewards and Incentives, Career Planning.
- Theories of Motivation, Motivational Techniques.
- Group Dynamics.
- Interpersonal Skills.

4. Operations Management

(08 Hours)

- Project Management.
- Product Design.
- Importance of Processes.
- Process Capabilities and Statistical Quality Control.
- Planning and controlling the supply chain: Forecasting, Aggregate Sales and Operations Planning, Inventory Control, Material Requirement Planning, Operation scheduling.
- Productivity Tools: ERP, MRP.

5. Financial Management

(06 Hours)

- Overview and introduction
- Financial statements: Taxes and Cash Flow
- Break Even Analysis
- Techniques of Capital Budgeting

6. Quality Management

(06 Hours)

- Introduction to statistical Methods
- Statistical Quality Control Tools
- Statistical Tools for Decision making
- Total Quality Management/ Kaizen: Six Sigma, Quality Circle.
- CPM

7. Distribution Management

(05 Hours)

- Managing Retailing, Wholesaling and Logistics

8. Corporate Governance

(05 Hours)

- Ethics.
- Shareholders Value Creation.
- Corporate Social Responsibility (CSR)

9. Systems Management

(02Hours)

- Management Information System (MIS)
- Database Management System (DBMS)

PRACTICALS

150 Hours (6Hrs/wk)

Student shall submit a journal consisting a write-up on Job description of different levels of employees each from different function and give employee evaluation controls (e.g. one for distribution dept., one for finance dept, one in administration, one in marketing & production dept.)

Student shall also submit a journal consisting a write-up on case studies and their analysis covering the various principles outlined in theory

- **Case Studies-** 15 Cases shall be analyzed based on topics of Principles of Management, Organizational behaviour and HRM, globalization- Mergers and acquisitions
- **Group Discussions** -10 based on problem –solving areas
- 2 role plays , movie presentations, video clips
- Problem solving to decide upon project choices and investment decisions

SCHEME OF ANNUAL PRACTICAL EXAMINATION

1. Synopsis	15 marks
2. Case study	30 marks
3. Group discussion	20 marks
4. Problem solving to decide upon project based on Choices and Investment decisions (Quantitative techniques)	15 marks
5. Viva voce	20 marks

TOTAL

100 marks

Text Books:

1. Management - A Global Perspective by Heinz Weirich, Harold Koontz (Latest Edition), Published by McGraw-Hill.
2. Management : Tasks, Responsibilities, Practices by Peter F. Drucker (Latest Edition), Published by Harpar Business.
3. Organizational Behavior by Stephen Robins (Latest Edition), Published by Prentice-Hall Pvt Ltd.
4. A textbook of Human Resource Management by C B Mamoria, S.V.Gankar (Latest Edition), Published by Himalaya Publishing House.
5. Financial Management: Theory and Practice By Prasanna Chandra (Latest Edition), Published by Tata McGraw-Hill.
6. Operations Management: A Competitive Advantage by Richar B Chace, F Robert Jacobs, Nicholas Aquilano (Latest Edition), Published by Tata McGraw-Hill.
7. HRD Audit By T V Rao (Latest Edition), Published by Sage Publication Pvt Ltd.
8. Sales Management- Decisions Strategies and Cases by Richard R Still, Edward W. Cundiff, Norman A.P. Govoni (Latest Edition), Published by Prentice-Hall Pvt Ltd.

Reference Books:

1. Human Resource Management and Industrial Relations by S .V.Subba Rao (Latest Edition), Published by Himalaya Publishing House.
2. Quantitative Techniques by C.R.Kothari (Latest Edition), Published by Vikas Publishing House Pvt Ltd.
3. Organizational Behaviour by Dr. K. Aswathappa (Latest Edition), Published by Himalaya Publishing House.
4. Productions and Operations Management by Dr. K. Aswathappa, K. Shridhara Bhat (Latest Edition), Published by Himalaya Publishing House.
5. Organisational Behaviour by Fred Luthans (Latest Edition), Published by Mc-Graw Hill International Edition

JOURNALS:

1. Pharmaceutical Executive
2. IDMA Bulletin
3. Pharma Biz
4. Pharma Pulse
5. The Pharma Review

PERIODICALS / JOURNALS / MANAGEMENT

1. HBR
2. Indian Journal Of Management

PAPER IV. PRODUCTION MANAGEMENT AND REGULATORY AFFAIRS

GOAL: To make the candidate completely familiar with statutory plant design, production planning, statutory regulations of production, formulation techniques.

OBJECTIVES: Upon completion of study candidate shall be able to

- Thoroughly understand the rules and regulations related to the manufacture and sale of drugs, understand and evaluate quality
- Attain an in-depth understanding knowledge about pharmaceutical service, facilities, material handling, and safety aspects
- To gain awareness in developing formulations as per statutory requirements.
- To gain knowledge in production planning, inventory control and forecasting.
- Exposure to industrial aspects of Pharmaceutical manufacture.

COURSE DESCRIPTION

THEORY

50 Hours (2Hrs/wk)

1. Dosage Form Manufacturing

(06 Hours)

Sterile and Non Sterile Dosage Forms

Introduction to Pilot plant scale- up techniques

Packaging

2. Validation and Quality Management

(09 Hours)

- Basics of validation, Concept, merits, types
- Concept of Quality Assurance, Quality Control, GMP, cGMP
- Lean Manufacturing, Just in Time, 5S, Kanban system
- Introduction to ISO 9000 & 18000 series,
- ICH guidelines with respect to API and formulations pertaining to Quality, safety and efficacy .

3. Intellectual Property Management (06 Hours)

Intellectual property Rights (Patents, Trademark and Copyrights), Patents: types, filing procedure, infringement issues, Hatch Waxman act, PCT Filing.

4. Supply Chain Management (04 Hours)

Supply Chain Design, Supply Chain Strategy and Logistic management

5. Production Planning, Scheduling and Forecasting (06 Hours)

Production planning and inventory control management, vendor development, assessment of production rate changes.

6. New Drug Discovery and Development (08 Hours)

Brief introduction of Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA).

7. Overview of Current Pharmaceutical Policy (03 Hours)

8. Various regulatory agencies worldwide like (08 Hours)

USFDA, TGA, MHRA, EMEA, MCC, ANVISA, SFDA, MHLW and CDSCO

PRACTICALS

100 Hours (6 Hrs/wk)

1. CASE STUDIES related to IPR infringement issues, Supply Chain management, Drug approval procedures and Production problems. Total 8 Case Studies (Major)
2. Comparative evaluation of Packaging guidelines of various regulatory agencies. (Minor)
3. Comparative evaluation of Labeling guidelines of various regulatory agencies (Minor)
4. Formulation of solid dosage forms and evaluation of excipients used in its formulation. (Major)
5. Formulation of liquid dosage forms and evaluation of excipients used in its formulation. (Major)
6. Formulation of semisolid dosage forms and evaluation of excipients used in its formulation. (Major)
7. Evaluation of Packaging Materials: Glass, Metal and Rubber (Minor)

Text Books:

1. The Theory and Practice of Industrial Pharmacy Leon Lachman, Ph.D., Lachman Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates, Inc. Consultant Services, Livingston, New Jersey. Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc. Ridgefield, Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400 0 14. 1987.
2. Pharmaceutical Dosage Forms and Drug Delivery System Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G Popovich, Ph.D., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia. London. 1990.
3. Drugs and Cosmetics Act, Vijay Malik, Latest edition. Eastern Publishers.
4. FDA regulatory affairs: A guide for prescription drugs, medical devices and biologics by Douglas J. Pisano and David S Mantus Publisher: CRC press
5. IPR handbook for Pharma students and researchers by Parikshit Bansal. Publisher: Pharma Book Syndicate

6. Production Planning and control- Text and cases by S K Mukhopadhyaya Publisher: Prentice Hall India
7. New Drug Approval Process by Richard A Guarino M. D. Publicer: Informa Health Care
8. Rohilla, Dhulichand; Dureja, HarishDr., New Drug Approval Process: Regulatory View, Pharmainfo.net, 2010.
9. Governement and regulatory bodies around the world, pharmweb.net/pwmirror/pwk/pharmwebk.html.
10. Meadows, M. The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective (2002). fda.gov/fdac/features/2002/402_drug.html
11. Rusell, R.S. & Taylor, B.W., "Operations Management, WSE, 5th Ed., 2006
12. Adam, E.E and Ebert, R.J., Production & Operations Management, 5th Ed., PHI, 1993.
13. Piringer OG, Baner AL. Plastic Packaging: Interactions with Food and Pharmaceuticals. John Wiley & Sons; 2008.
14. Jenke D. Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products. John Wiley & Sons; 2009.
15. Theobald N, Winder B. Packaging Closures and Sealing Systems. John Wiley & Sons; 2009.
16. Bauer E. Pharmaceutical Packaging Handbook. Informa Healthcare; 2009.
17. Dean DA, Evans R, Hall I. Pharmaceutical Packaging Technology. Taylor & Francis; 2000.
18. Calver G. What Is Packaging Design? Rotovision; 2007.
19. http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm
20. http://www.isohelpline.com/iso_ohsas_18000_18001_2007_document_manual.htm
21. www.ich.org/
22. www.ich.org/products/guidelines/quality.html

Reference Books:

1. Modern Pharmaceutics, Second Edition, Revised & Expanded (Volume 40) Edited by Gilbert S. Banker'; University of Minnesota, Minneapolis, Minnesota; ChristopherT. Rhodes, University of Rhode Island, Kingston, 1990 Marcel Dekker Inc., 270 Madison Avenue, New York 10016.
2. Controlled Drug Delivery (Volume 29) Fundamentals & Applications Second Edition, Revised and Expanded Edited by Joseph R. Robinson, School of Pharmacy, University of Wisconsin, Madison, Wisconsin; Vincenth L. Lee, School of Pharmacy, University of Southern California, Los Angeles, California, 1987 Marcel Dekker, Inc., 270 Madison Avenue, New York, New York 10016.
3. Remington's Pharmaceutical Sciences, 20th Edition - 2001 Editors: Atthur Osol, Grabton D. Chase, Alfonso R. Gennaro, Melvin R. Gibson, C. Boyd Granberg, Stewart C. Harvey, Robert E. King, Alfred N. Martin, EwartA. Swinyard, Gilbert L. Zink Published in the 160th year of the Philadelphia College of Pharmacy and Science.
4. Pharmaceutical Dosage Forms - Tablets: Second Edition, Revised and Expanded in three volumes Volume - 3 Edited by Herbert A. Lieberman, H.H. Lieberman Associates, Inc., Consultant Services, Livingston, New Jersey. Leon Lachman, Lachman Consultant Services, Westbury, New York. Joseph B. Sch)Vartz, Philadelphia College of Pharmacy and Science, Philadelphia, Pennsylvania. 1990 by Marcel Dekker, Inc., 270 Madison Avenue, New York 10016.
5. Pharmaceutical Dosage Forms - Disperse Systems Edited by Herbert A. Lieberman . Rieger and Gilbert S. Banker, 1989, Marcel Dekker, Inc. 270 Madison Avenue, New York 10016.
6. Material Management by K.K. Ahuja, Published by: CBS Publishers and Distributors, 1992

JOURNALS

1. Indian Journal of Pharmaceutical Sciences
2. IDMA Bulletin
3. Pharma Biz
4. Indian Drugs

SCHEME OF ANNUAL PRACTICAL EXAMINATION:

1.Synopsis	20 Marks
2 Major Experiment (Case Study Presentation or Laboratory Experiment)	40 Marks
3. Minor Experiment (Case Study Presentation or Laboratory Experiment)	20 Marks
4.Viva	20 Marks
TOTAL:	100 Marks

Note: Case study presentation should be the part of examination as either major or minor experiment.