

PHARMACEUTICAL MANAGEMENT

DETAILED SYLLABUS

For

MASTER OF BUSINESS ADMINISTRATION

(Applicable for the batches admitted from 2021-22)



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
KAKINADA – 533003, ANDHRA PRADESH, INDIA

I YEAR I SEMESTER							
S.No	CourseCode	Courses	Marks	L	T	P	C
1	C-101	Management and Organizational Behavior	100	4	0	0	4
2	C-102	Managerial Economics	100	4	0	0	4
3	C-103	Accounting for Managers	100	4	0	0	4
4	C-104	Quantitative Analysis for Business Decisions	100	4	0	0	4
5	C-105	Legal and Business Environment	100	4	0	0	4
6	C-106	Business Communication and Soft skills	100	2	0	2	4
7	C-107 Open Elective	Cross Cultural Management Rural Innovation projects MOOCs : SWAYAM/NPTEL- Related to Management Courses other than listed courses in the syllabus	100	4	0	0	4
8	C-108	Information Technology – Lab1(Spreadsheet and Tally)	50	0	0	2	2
Total			750	28	0	2	30

I YEAR II SEMESTER							
S.No	Course Code	Courses	Marks	L	T	P	C
1	C-201	Financial Management	100	4	0	0	4
2	C-202	Human Resource Management	100	4	0	0	4
3	C-203	Marketing Management	100	4	0	0	4
4	C-204	Operations Management	100	4	0	0	4
5	C-205	Business Research Methods	100	4	0	0	4
6	C-206 open elective	Project Management Technology Management Lean Management Database Management System	100	4	0	0	4
7	C-207	IT-lab 2(Programming R)	50	0	0	2	2
Total			650	24	0	2	26

II YEAR III SEMESTER							
S.No	Course Code	Courses	Marks	L	T	P	C
1	C-301	Strategic Management	100	4	0	0	4
2	C -302	Operations Research	100	4	0	0	4
3	EP -301	Elective – 1	100	4	0	0	3
4	EP-302	Elective – 2	100	4	0	0	3
5	EP-303	Elective – 3	100	4	0	0	3
6	EP-304	Elective – 4	100	4	0	0	3
7	C-304	Industrial Project based on Summer Internship	150	4	0	0	4
Total			750	28	0	0	24

II YEAR IV SEMESTER							
S.No	Course Code	Courses	Marks	L	T	P	C
1	C -401	Supply Chain Management and Analytics	100	4	0	0	4
2	C-402	Innovation and Entrepreneurship	100	4	0	0	4
3	EP-401	Elective – 5	100	4	0	0	3
4	EP-402	Elective – 6	100	4	0	0	3
5	EP-403	Elective – 7	100	4	0	0	3
6	EP-404	Elective – 8	100	4	0	0	3
7	C-403	Comprehensive Viva- voce	50	0	0	0	2
Total Marks / Credits			650	28	0	0	22
			2800				102

*The project work documentation shall be checked with anti plagiarism software (Turnitin). The permissible similarity shall be less than 30%.

*Comprehensive Viva is to verify the student knowledge as a whole from which he was studied during the twoyear course work.

**III-SEMESTER
PHARMACEUTICAL MANAGEMENT**

S. No	Course Code	SUBJECT TITLE
1	EP-301	Pharmaceutical Business Environment
2	EP-302	Pharmaceutical Production, Operations and Quality Management
3	EP-303	Pharmaceutical Marketing
4	EP-304	Pharmaceutical Product and Brand Management
5	EP-305	Pharma Industry in International Marketing

**IV-SEMESTER
PHARMACEUTICAL MANAGEMENT**

S. No	Course Code	SUBJECT TITLE
1	EP-401	Drug Regulatory Affairs & Intellectual Property Rights (DRA& IPR)
2	EP-402	Ethical Issues in Pharmaceutical Management
3	EP-403	International Marketing
4	EP-404	Pharmaceutical Advertising & Services Management
5	EP-405	Regulatory Affairs in Pharma

**MBA-III Semester Syllabus
For
Pharmaceutical Management
Pharmaceutical Business Environment**

EP-301	Pharmaceutical Business Environment	100	4	0	0	3
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Objective:

The course aims at understanding of several factors affecting the business and business operations. This course enables students to learn about business policies, ethical codes and different factors responsible for changing dimensions of corporate environment

Unit I: Introduction to Business Environment Meaning & Importance of Business Environment Dimensions of Business Environment, Impact of Internal & External Environment of Business on Pharmaceutical Industry.

Unit II : Environmental, Political, Social and Economical cultural environment of pharmaceutical business Various Processes for Environmental Analysis, PEST Model, Structural Industry Analysis (Porter's Five Forces), SWOT Analysis, Changing Market Access Strategies in Pharmaceutical Industry Concept of Economic Environment of Business, Component (fiscal and monetary policy) and development (pre-globalisation), Political legal environment for pharmaceutical business.

Unit III: Evolution of Indian Pharmaceutical Industry Global Pharmaceutical Business Environment Different Evolution Phases of Indian Pharmaceutical Industry, Present status of Indian Pharma Industry (Present value, Key Players, Indian Bulk Drug Market).

Unit IV : International and technological environment: Global Pharma Developments, Multinational Corporation, Mergers & Acquisitions of pharmaceutical industry at global level & India level, International Financial Environment (FDI, FDI in Drugs & Pharmaceuticals).

Unit V: Strategies & Trends – Research & Development in Pharmaceutical Industries Various types of Research, R& D Funds, Pharmaceutical research and development support fund (PRDSF), R&D Opportunities, and Contract research Opportunities, Research in generics, changing the conventional façade of drug discovery research, Six Sigma and its approach to drug discovery.

(Case Studies are compulsory)

Text & References:

1. Business Environment by F. Cherunilam, Himalaya Publishing House, Revised edition-2019
2. Business Environment by Raj Aggarwal and Parag Diwan,2002
3. Government and Business by N K Sengupta,1999
4. Technology and Economic Development The Indian Case by Debashish Mallick,2014
5. Business Laws by N D Kapoor, 2019
6. Business Policy and Strategic Management by W F Glueck and Jauch, 1988
7. Pharmaceutical Industrial Management, Shah, 2010
8. Pharmaceutical Marketing in India, Subba Rao, 2018

Pharmaceutical Production, Operations and Quality Management

EP-302	Pharmaceutical Production, Operations and Quality Management	100	4	0	0	3
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Objective:

The paper aims to provide the students with a knowledge base to promote the use of best practices and operational excellence within pharmaceutical operations management. The course addresses all operations right from the introduction to operations management, facilities planning, production planning, and selection of raw materials through to the quality aspect of final product.

Unit I: Introduction to production and operations management Definition, concept and Evolution of Production and operations management, Nature and Scope of production/operations management, Production function and its environment, Functions of production/operations manager, Organization of production function in Pharma industry

Unit II: Facilities planning, Layout planning Product selection and design, service design, Process and technology, selection, Location of manufacturing/service facility, Center of gravity and median models, dimensional analysis, Brown and Gibson model.

Product layout, process layout, fixed position and group layout, layout design, Relationship based and load-distance cost matrix, Materials handling concepts.

Unit III: Production planning, Materials planning and control, Need and definition, factors affecting planning- external and internal, dependent and independent demand system, techniques of planning, Materials Requirement Planning,

Aggregate production planning, Operations Scheduling and Production activity control for mass manufacturing, batch processing

Unit IV: Drug and Pharmaceutical Plants, Resources Requirement Planning Building layout, equipment layout, regulatory requirements for the same, GMP and cGMP
Capacity Planning, Labour Planning,

Unit V: Inventory Control & Quality Control & Management Inventory Control: Importance and scope, costs, economic order quantity, Inventory control techniques.

Quality control functions, Acceptance sampling, Statistical Process control, Application of control charts, Operating characteristic curve and its applications, Total Quality improvement, six sigma.

(Case Studies are compulsory)

Text & References:

1. Operations Management by Bernard Taylor, 2011
2. Production and Operations Management by Adam, Ronald and Ebert, 1992
3. Production and Operations Management by Aswathappa and Bhat, 2010
4. Pharmaceutical Operations Management: Manufacturing for Competitive Advantage, 2016
5. Pharmaceutical Quality Assurance, 2006
6. Concepts of Quality Management in Pharmaceutical Industry, 2017
7. Concepts of Quality Management in Pharmaceutical Industry (English, Paperback, Manohar A. Potdar), 2016

Pharmaceutical Marketing

EP-303	Pharmaceutical Marketing	100	4	0	0	3
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Objective:

The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.

UNIT I: Marketing: Definition, general concepts, and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis

Pharmaceutical market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting; Analyzing the Market, Role of market research.

UNIT II: Product decision: Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; new product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

UNIT III: Promotion: Meaning and methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

UNIT IV: Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels

Physical distribution management: Strategic importance, tasks in physical distribution management: duties of Physical Sales Representative, purpose of detailing, selection and training, supervising, motivating, evaluating, compensation and future prospects of the Physical Sales Representative.

UNIT V: Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

(Case Studies are compulsory)

Text Books & References:

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi, Fifteen edition, 2017
2. Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata McGrawHill, New Delhi, 2017
3. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw Hill, 1994
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India, January 2016
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition), 1 July 2017.
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, IndianContext, Macmillan India, New Delhi, June 2012.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi, July 2017
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications, October 2018.

Pharmaceutical Product and Brand Management

EP-304	Pharmaceutical Product and Brand Management	100	4	0	0	3
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Objective:

The course aims at an understanding of pharma product and brand management skills and techniques that are commonly applied in industry. The course has been designed to provide an effective training on concepts as well as practical knowledge related to pharma products and brands and to help learners nurture their idea by taking them through the entire product lifecycle.

Unit I: Introduction to Product Management Definition, role of product management and scope of product management, product levels, societal classification of the product by Kotler, classification of pharma products, market research and its contribution in product development and management

Unit II: New Product Development, Product Mix and Product life-cycle Definition of new product, type of new products, product innovation, Roger's diffusion of innovation curve, technology product life cycle management, product portfolio management strategies, product mix and product line strategies, product life cycle concept and its linkage with the pharmaceutical industry.

Unit III: Product Planning and Pricing Strategies Introduction, objectives of product planning, components of product planning, product portfolio planning, product-line decisions, product mix decisions, pricing, importance of price, objectives of pricing, factors influencing the price determination, pricing policies, pricing methods or determination or the price of pharma product.

Unit IV: Branding of the Pharma Products What is a Brand: History, branding elements-brand identity, brand personality, brand communication, Brand Name, Brand Image, Brand Value and Brand Awareness, Concept of Brand Equity, difference with brand valuation, Five dimensions of Brand Equity, key influencers of each dimension, prescription loyalty, prescriber coverage frequency, brand exposure through field-force promotion, Quality indicators, Promotional-mix, Benefits of building Brand Equity, brand positioning and difference with consumer brands, Branding process, pharma branding process and strategies, OTC generic and prescription product branding, reinforcing and revitalizing pharmaceutical brands.

Unit V: Pharma Product Promotion Defining promotion, promotional strategies, issues in pharma product promotion, approaches for pharma product promotion Product-mix Optimization & Promotional-mix Optimization: Portfolio Analysis by factoring key determinants, BCG Matrix, brand building decisions; leveraging the Promotional-mix for Brand Building.

(Case Studies are compulsory)

Text & References:

1. Product Management in India by Majumdar, R.2007
2. Marketing Management: Planning by Ramaswamy, V.S. and Namakumari, S. Marketing byZikmund, A. July 2018.
3. Innovating Organization, edited by Pettigrew &Fenton, 2000.
4. Marketing Research - Measurement and Method by Tull andHawkins, 1993.
5. Strategic Brand Management by Kevin Keller, Pearson 2013.
6. Brand Positioning by Sen Gupta, 2nd Edition 2005.
7. Managing Indian Brands by Ramesh Kumar, 2003

Pharma Industry in International Marketing

EP-305	Pharma Industry in International Marketing	100	4	0	0	3
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Objective:

With successful completion of this course students will learn: To develop an understanding of major issues related to international marketing and also enabled to develop skills in researching and analyzing trends in global markets and in modern marketing practice. They will be able to assess an organization's ability to enter and compete in international markets

Unit I: Basics of International Pharmaceutical Marketing Introduction to Pharmaceutical Marketing, Scope of International Pharmaceutical Marketing, International Marketing vs. Domestic Marketing, Principles of International Marketing, Competitive or differential advantage, Management Orientations, MNCs and TNCs, Benefits of international marketing.

Unit II: International Marketing Environment Introduction, Political Environment, Political systems, legal and Regulatory Environment, Socio-cultural Environment, Economic Environment, Technological Environment, Challenges in Global Marketing.

Unit III: International Trade Organization (GATT, WTO) Introduction, classical trade theories, modern trade theories, trade barriers, quotas, Implications of Tariffs, Types of Agreements, General Agreement on Tariffs and Trade (GATT), Functions and Objectives of WTO, Implication of WTO on International Marketing, India's Role in International Trade theories.

Unit IV: International Marketing Research Introduction, Concept of Marketing Research, Need for Marketing Research, Approach to Marketing Research, Scope of International Marketing Research, International Marketing Research Process, market surveys, marketing information system

Unit V: International Pricing Policy, Negotiation and Decision Making Introduction, Price and Non-Price Factors, Methods of Pricing, International Pricing Strategies, Dumping and Price Distortion, Counter Trade Negotiating with Intentional Customers, Partners, and Regulators, Global E-marketing.

(Case Studies are compulsory)

Text & References:

1. International Marketing, 6th edition, ISBN 981-240-244-6, by Subhash C. Jain. 1994
2. Masaaki Kotabe, Kristian Helsen "Global Marketing Management" 2000.
3. Joshi, Rakesh Mohan – International Marketing, November 2014.
4. Simon Majaro- International Marketing, 2013
5. Export Marketing by B.S. Rathore, 1993
6. Export Procedures and Documents by S.C. Jain, 2011.
7. Global Marketing by Keegan, 2013

**MBA –IV SEMESTER
PHARMACEUTICAL MANAGEMENT**

S. No	CourseCode	SUBJECT TITLE
1	EP-401	Drug Regulatory Affairs & IntellectualProperty Rights (DRA& IPR)
2	EP-402	Ethical Issues in Pharmaceutical Management
3	EP-403	International Marketing
4	EP-404	Pharmaceutical Advertising & Services Management
5	EP-405	Regulatory Affairs in Pharma

MBA –IV SEMESTER
PHARMACEUTICAL MANAGEMENT
Drug Regulatory Affairs & Intellectual Property Rights (DRA & IPR)

EP-401	Drug Regulatory Affairs & Intellectual Property Rights (DRA & IPR)	100	4	0	0	3
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Objective:

After the completion of course students are able to perform the patent search and having knowledge about patent drafting, the student also learn about managing the documents related to CTD, DMF and dossier as per the regulatory guidelines. The students also gain knowledge about the national and international guidelines pertaining to pharmaceutical regulatory framework. They can perform various assignment related to pharmaceutical regulatory scientist in industry.

Unit I: Drug Regulation History of drug regulation in India, Indian drug regulatory system, The Drug and Cosmetics act, Global environment regulation, Regional collaboration for drug regulation.

Unit II: Drug approval process Filing of INDA, NDA & ANDA in USFDA, International licensing in EU countries, International licensing in African and Asian countries, API regulatory process in pharmaceutical industry.

Unit III: Industrial Documentation Clinical data systems, Electronic submission, File Formats for electronic documents, Procedure for sending electronic submission for archive, ICH M2-eCTD/ International Standardization efforts

Unit IV: Pre TRIPS & WTO Introduction of IPR , Types of Intellectual property Rights, Copy Right Registration, Agencies Responsible for Intellectual Property Registration, Indian Patent law in Pre TRIPS, World Trade Organization (WTO).

Unit V: Intellectual Property Right (IPR) Introduction to various IPR, Development of IP law in India, Introduction of IP law in India, World Intellectual Property Organization (WIPO), Patent Filing in India, Patent law & Indian pharmaceutical industries, Drug patent challenges in US, Regional collaboration for drug regulation, Patent Infringement.

(Case Studies are compulsory)

Text Books & References:

1. Intellectual Property Rights and Drug Regulatory Affairs, Ruchi Tiwari and Gaurav Tiwari, 2020
2. Intellectual Property Rights in Pharma Indus, Subba Rao, 2018
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions/Sandy Weinberg, John Wiley & Sons. Inc.
5. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
6. Quality Assurance of Pharmaceuticals- A compedium of guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
7. Pharma Book Syndicate by N.R. Subbaram, 2003
8. TRIPS and pharmaceutical industry by Manish shiya
9. Patent Management, Oliver Gassmann, Martin A. Bader, Mark James Thompson. Sprinzer Nature Publisher

ETHICAL ISSUES IN PHARMACEUTICAL MANAGEMENT

EP -402	Ethical Issues in Pharmaceutical Management	100	4	0	0	3
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Objective:

The aim would be to make participants understand legal boundaries within which the pharma industry operates, and also to make them understand the ethical aspects of managing pharma industry.

UNIT I: Social responsibility and managerial ethics, Improving ethical behaviour and ethical leadership, Ethical decision making and decision making process, Theories of Business Ethics

UNIT II: Ethics in Marketing: Product safety and Pricing-Ethical responsibility in Product-Advertising and Target Marketing Ethics of sales, advertising and product placement and Consumer Autonomy.

UNIT III: Ethics in HRM & Finance – HR related ethical issues - Institutional Culture – Frauds in drugs - Measures against Frauds in drugs – Frauds in Pharma sector

UNIT IV: Corporate social responsibility, Corporate Governance, Whistle blower and Whistle blower policy, managing diversity war gender, race, ethnicity etc.

UNIT V: Indian model of Governance- Good Corporate Governance – Land marks in emergence of Governance OECD Principles, Role of Government in Ensuring Corporate Governance – Governance issues relating to Board of Directors - Role of Media

(Case Studies are compulsory)

Text Books & References:

1. S.K. Mandal: “Ethics in Business and Corporate Governance”, TMH, New Delhi, 2012.
2. Marianne M Jennings: “Cases in Business Ethics”, Cengage Learning, New Delhi, 2012.
3. S. Prabhakaran: “Business Ethics and Corporate Governance”, Excel Books, New Delhi, 2011.
4. N. Balasubramanyam: “A Case Book on Corporate Governance and Stewardship”, TMH, New Delhi, 2011.
5. A.C. Fernando: “Business Ethics and Corporate Governance”, Pearson Publishers, New Delhi, 2013.
6. Ethics in Human Resource Management, Dr. Srinju Kapoor, Prof Kotta Ramesh, Discovery Publishing, 2020

INTERNATIONAL MARKETING

EP -403	International Marketing	100	4	0	0	3
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Unit I: Product Policy and Planning for International Markets Introduction, Products, the new Product Development, National and International Product Planning, Product Adoption and Standardization, International Market Segmentation, Influences on Marketing Plan and Budget, International Product Marketing

Unit II: Terms of Payment and Delivery Advance of payment, Open Account System, Consignment Sale, Documentary Collection, types of payment, types of dumping, counter trade, transfer pricing, Grey marketing

Unit III: International Logistics and Distribution Planning

Introduction, International Distribution, Direct and Indirect Channels, Factors involved in Distribution Systems, Value Chain Concept, Modes of Transportation.

Unit IV: Communication Decision for International Markets and International Financial Institutions Introduction to Communication in Marketing, Global Communication Strategy, Factors influencing Communication decisions. Introduction, IMF, World Bank – IBRD, International Finance Corporation.

Unit V: Export Procedures, Policies and Export Documentation

Procedure of Export- Example of Export Procedure, Enquiry, Quotation, Order Receipt and Acceptance, Finance, Production and Packing, Excise Clearance, Export Documents, Cargo Insurance and Shipping Space Reservation, Customs Clearance, Receipt of Shipment Documents from C&F Agent, Presentation of Shipment Documents to the Negotiating Bank, Presentation of Documents for Payment to Foreign Bank by the Negotiating Bank, Significance of Export Documentation, Declaration Forms, Export Documentation Requirements in India-

(Case Studies are compulsory)

Text Books & References:

1. International Marketing, 6th edition, ISBN 981-240-244-6, by Subhash C. Jain.
2. Masaaki Kotabe, Kristian Helsen “Global Marketing Management”, 2010
3. Joshi, Rakesh Mohan – International Marketing, 2005
4. Simon Majaro- International Marketing, 1979
5. Export Marketing by B.S. Rathore, 2015
6. Export Procedures and Documents by S.C. Jain, 2013
7. Global Marketing by Keegan, 2013

PHARMACEUTICAL ADVERTISING & SERVICES MANAGEMENT

EP -404	Pharmaceutical Advertising & Services Management	100	4	0	0	3
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UNIT I: Services marketing - meaning - nature of services - Types and importance - Relationship marketing, Mission, strategy, elements of service, service marketing plan & market segmentation.

UNIT II: Marketing mix decisions – unique features of developing, pricing, promoting and distributing services – positioning and differentiations strategies quality of service industries – achievement and maintenance, customer support service

UNIT III: Nature and scope of advertising, advertising methods, advantages and disadvantages of advertising, advertising design and development, Advertising control and Public Relationship.

UNIT IV: Nature and Pharmaceutical Services: – Understanding the pharma services and clinics. Understanding after sales services for any medical and pharmaceutical instruments.

UNIT V: Hospital Services and Non -Profit Organization services- Services provided in hospitals and offered by charities – Educational Services – Miscellaneous Services – Power and Telecommunication.

(Case Studies are compulsory)

Text Books & References:

1. Services Marketing: Valarie A. Zeithaml & Mary Jo Bitner, Integrating Customer Focus Across The Firm, Third Edition, 2004.
2. Services Marketing: Christopher H. Lovelock, Jochen Wirtz, Jayanta Chatterjee, People, Technology, Strategy (A South Asian Perspective) Fifth Edition 2017; Pearson Education
3. Services Marketing- love lock – Prentice Hall, 2021
4. Services Marketing- S.M. Jha, Himalaya Publishing Company, 1998, Mumbai
5. Services Marketing- Principles and Practice - palmer, Prentice Hall, 1995

REGULATORY AFFAIRS IN PHARMA

EP -405	Regulatory Affairs In Pharma	100	4	0	0	3
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Objective:

This course is design to impact advanced knowledge and skills required to learn the concepts of generic drug and their development, various regulatory filing in different countries, regulatory documents.

Good manufacturing practice (GMP), Good laboratory practice (GLP), Good Automated laboratory practice (GALP), Good distribution practice (GDP), Quality management Documentation in pharmaceutical industry: EPDB, PDP, PDR. CoA, DMF Filing process: IND, NDA and ANDA Dossier preparation and submission Audits and inspections Product life cycle management Global regulatory strategies for pharmaceuticals.

UNIT I: Pharmaceutical Legislations – Drugs & Pharmaceutical Industry –Pharmaceutical Education – Pharmaceutical Ethics - A brief review.

UNIT II: Introduction and Principles of Forensic Science, Forensic Medicine and Toxicology, Medicinal Chemistry of Drugs of Abuse, and Other allied areas.

UNIT III: An elaborate study of the following: (A) Pharmacy Act 1948 (B) Drugs and Cosmetics Act 1940 and Rules 1945 [14] (C) Medicinal & Toilet preparations (Excise duties Act 1955) (D) Narcotic Drugs & Psychotropic Substances Act 1985 & Rules. (E) Drugs Price Control Order 1995.

UNIT IV: (A) Poisons Act 1919 (B) Drugs and Magic remedies (Objectionable Advertisements) Act 1954. (C) Medical termination of Pregnancy Act 1970 & Rules 1975.

UNIT V: (D) Prevention of Cruelty to Animals Act 1961. (E) States Shops & Establishments Act & Rules. (F) A.I.C.T.E. Act 1987 (G) Patents Act 1970 (H) Weight and Measures Act (I) Package and Commodity Act (J) U.S Food and Federal D&C Act, Case studies.

(Case Studies are compulsory)

Text Books & References:

1. B.M., Mittal, Textbook of Forensic Pharmacy, National Book Centre, Dr. Sundari Mohan Avenue, Calcutta. 2017
2. Drugs & Cosmetics Act, 1940
3. Drugs & Cosmetics Act, 2008
4. The Pharmacy Act, 1948
5. Drugs & Psychotropic Substances Act, 1985
6. Excise duties Act 1955
7. Relevant Acts & Rules Published by the Govt. of India