



School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

MBA PHARMA MANAGEMENT (1 year program)



Malla Reddy Vishwavidyapeeth

(Deemed to be University)

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Course Title: MBA IN PHARMACEUTICAL MANAGEMENT

Course Type: FELLOWSHIP (1Year Program)

Duration: 840 Hours (can be structured as 56 Credits)

Mode: Lectures, Practicals /Hands-on, Project

Overview

The MBA in Pharmaceutical Management is a specialized postgraduate program designed to develop professionals who are adept at managing the multifaceted aspects of the pharmaceutical industry. Aligned with the National Education Policy (NEP) 2020, this program integrates a multidisciplinary approach, focusing on innovation, critical thinking, and practical skills while maintaining the flexibility to cater to diverse learning needs.

The program is structured into two semesters, each consisting of a blend of core courses, electives, practical training, field Project and a research project. The curriculum is designed to provide a deep understanding of pharmaceutical management, covering areas such as drug regulatory affairs, pharmaceutical marketing, supply chain management, pharmacoeconomics, and intellectual property rights. Additionally, the program emphasizes the development of leadership, ethical decision-making, and strategic thinking skills.

Objectives:

The main objective of the **MBA Pharmaceutical Management Programme** is to equip students with the knowledge and skills necessary to manage and lead in the pharmaceutical and healthcare industries. The program integrates pharmaceutical sciences with business management principles, fostering expertise in drug development, marketing, regulatory affairs, and healthcare management, while promoting ethical practices, innovation, and global competitiveness.

The broad objectives of the Program are:

1. **Comprehensive Industry Knowledge:** Equip students with in-depth knowledge of pharmaceutical science and business management.
2. **Leadership Development:** Cultivate leadership and managerial skills tailored to the pharmaceutical sector.
3. **Innovation and Critical Thinking:** Promote innovation and problem-solving abilities in addressing industry challenges.
4. **Ethical and Sustainable Practices:** Instill ethical decision-making and a commitment to sustainability in pharmaceutical management.
5. **Global Competency and Employability:** Prepare students for global careers with a focus on pharmaceutical and healthcare industries.



Course Outcome:

CO No.	Course Outcome (Single-Sentence Statement)
C01	Recall fundamental concepts of drug development, clinical trials, regulatory frameworks, and explain the structure and functioning of pharmaceutical business models and healthcare systems.
C02	Apply managerial principles to solve operational challenges and analyze pharmaceutical supply chain case studies to identify gaps and propose effective solutions.
C03	Implement ethical pharmaceutical marketing practices and evaluate the effectiveness of sales and distribution strategies across diverse healthcare markets.
C04	Describe national and international drug laws, patents, and compliance requirements, and evaluate the impact of regulatory changes on pharmaceutical business operations.
C05	Analyze clinical and market data to assess the feasibility of new drug launches and create innovative business models or entrepreneurial ventures in healthcare and pharmaceuticals.
C06	Demonstrate leadership skills in managing cross-functional teams and develop strategic plans for sustainable business growth in pharmaceutical and healthcare sectors.

Teaching & Learning Methods:

- Interactive sessions: Engage in lively discussions and collaborative problem solving.
- Case based learning: Apply theoretical knowledge to real world scenarios through internship and case studies.
- Role playing: Enhance decision making skills through simulated scenarios
- Practical workshops: Gain hands on experience in key aspects of Supply chain and logistics management

M.B.A. PHARMACEUTICAL MANAGEMENT PROGRAME COURSE STRUCTURE

Semester I				
Type	Sem	Course	Theory/ Practical	Credits
Mandatory	SEM-I	Management Science	T	4
	SEM-I	Pharmacoeconomics	T	4
	SEM-I	Organisation Behaviour	T	4
	SEM-I	Business Accounting	T	2
	SEM-I	Business Communication	T	2
	SEM-I	AI Basics for Managers	T	2
Total				18
Elective	SEM-I	General Pharmacology & Pharmacoeconomics	T	4
	SEM-I	Operations Management	T	4
Total				4



RM	SEM-I	Research Methodology	T	4
Total				4
Total Credits				26
Semester II				
Type	Sem	Course	Theory/ Practical	Credits
Mandatory	SEM-II	Drug Regulatory affairs in Pharmaceuticals	T	4
	SEM-II	Indian Economy & Policies	T	2
	SEM-II	Human Resource Management	T	4
	SEM-II	Pharmaceutical Marketing Management	T	4
	SEM-II	Financial Management	T	4
	SEM-II	Pharmaceutical Industry Ethics	T	2
	Total			
Elective	SEM-II	Entrepreneurship & Start-up Ecosystem	T	4
	SEM-II	Sustainable Development	T	4
	SEM-II	SWAYAM/NPTEL/ MOOC Course	T	4
	Total			
OJT/FP/RP	SEM-II	Field Project		2
		Internship		4
Total				6
Total Credits				30
Cumulative credits (Semester I + Semester II)				56

Course Title: MBA IN PHARMACEUTICAL MANAGEMENT

Course Type: PG DIPLOMA

Duration: 360 Hours (can be structured as 56 Credits)

Mode: Lectures, Practicals, Internship, Project

Overview – Pharmaceutical Logistics Management

The MBA in Pharmaceutical Management is a specialized postgraduate program designed to develop professionals who are adept at managing the multifaceted aspects of the pharmaceutical industry. Aligned with the National Education Policy (NEP) 2020, this program integrates a multidisciplinary approach, focusing on innovation, critical thinking, and practical skills while maintaining the flexibility to cater to diverse learning needs.

The program is structured into two semesters, each consisting of a blend of core courses, electives, practical training, field Project and a research project. The curriculum is designed to provide a deep understanding of pharmaceutical management, covering areas such as drug regulatory affairs, pharmaceutical marketing, supply chain management, pharmacoeconomics, and intellectual property rights. Additionally, the program emphasizes the development of leadership, ethical decision-making, and strategic thinking skills.

Objectives of the Course

The main objective of the **MBA Pharmaceutical Management Programme** is to equip students with the knowledge and skills necessary to manage and lead in the pharmaceutical and healthcare industries. The program integrates pharmaceutical sciences with business management principles, fostering expertise in drug development, marketing, regulatory affairs, and healthcare management, while promoting ethical practices, innovation, and global competitiveness.

The broad objectives of the Program are:

1. **Comprehensive Industry Knowledge:** Equip students with in-depth knowledge of pharmaceutical science and business management.
2. **Leadership Development:** Cultivate leadership and managerial skills tailored to the pharmaceutical sector.
3. **Innovation and Critical Thinking:** Promote innovation and problem-solving abilities in addressing industry challenges.
4. **Ethical and Sustainable Practices:** Instill ethical decision-making and a commitment to sustainability in pharmaceutical management.
5. **Global Competency and Employability:** Prepare students for global careers with a focus on pharmaceutical and healthcare industries.

Course Outcomes:

C01: Pharmaceutical Industry Knowledge

- **Remember:** Recall fundamental concepts of drug development, clinical trials, and regulatory frameworks.
- **Understand:** Explain the structure and functioning of pharmaceutical business models and healthcare systems.

C02: Strategic & Managerial Skills

- **Apply:** Use management principles to solve operational challenges in pharma organizations.
- **Analyze:** Examine case studies to identify gaps in pharmaceutical supply chains and propose solutions.

C03: Marketing & Sales Competence

- **Apply:** Implement ethical marketing strategies for pharmaceutical products.
- **Evaluate:** Assess the effectiveness of sales and distribution strategies in diverse healthcare markets.

C04: Regulatory & Legal Awareness

- **Understand:** Describe national and international drug laws, patents, and compliance requirements.
- **Evaluate:** Judge the impact of regulatory changes on pharmaceutical business operations.

C05: Research & Innovation

- **Analyze:** Interpret clinical and market data to assess feasibility of new drug launches.
- **Create:** Design innovative business models or entrepreneurial ventures in healthcare and pharma.

C06: Leadership & Professional Readiness

- **Apply:** Demonstrate leadership skills in managing cross-functional teams.
- **Create:** Develop strategic plans for business growth in pharmaceutical and healthcare sectors.

Teaching learning methods:

- Interactive sessions: Engage in lively discussions and collaborative problem solving.
- Case based learning: Apply theoretical knowledge to real world scenarios through internship and case studies.
- Role playing: Enhance decision making skills through simulated scenarios
- Practical workshops: Gain hands on experience in key aspects of human resource management, operational management, Supply chain and logistics management

M.B.A. PHARMACEUTICAL MANAGEMENT PROGRAME COURSE STRUCTURE

Type	Sem	Course	Theory/ Practical	Credits
Mandatory	SEM-I	Management Science	T	4
	SEM-I	Pharmacoeconomics	T	4
	SEM-I	Organisation Behaviour	T	4
	SEM-I	Business Accounting	T	2
	SEM-I	Business Communication	T	2
	SEM-I	AI Basics for Managers	T	2
		Total		18
Elective	SEM-I	General Pharmacology & Pharmacoepidemiology	T	4
	SEM-I	Operations Management	T	4
		Total		4
RM	SEM-I	Research Methodology	T	4
		Total		4
Cumulative Credits/Sem		Semester-I Total Credits		26
Type	Se m	Course	Theory/ Practical	Credits
Mandatory	SEM-II	Drug Regulatory affairs in Pharmaceuticals	T	4
	SEM-II	Indian Economy & Policies	T	2
	SEM-II	Human Resource Management	T	4
	SEM-II	Pharmaceutical Marketing Management	T	4
	SEM-II	Financial Management	T	4
	SEM-II	Pharmaceutical Industry Ethics	T	2
		Total		20
Elective	SEM-II	Entrepreneurship & Start-up Ecosystem	T	4
	SEM-II	Sustainable Development	T	4
	SEM-II	SWAYAM/NPTEL/ MOOC Course	T	4
		Total		4
OJT/FP/RP	SEM-II	Field Project		2
		Internship		4
		Total		6
		Semester-II Total Credits		30
		SEMESTER -I & SEMESTER -II TOTAL		56

Syllabus

SEMESTER I

Course 1: Management Science**Total Credits: 04****Lecture Hours: 48 Hours****Course Type: Mandatory Course DSC****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit – I Foundation of Management Concepts 1.1. Management: Concept, Nature, scope, purpose, functions & Importance 1.2. Management: Art and Science & as a Profession, Management Vs Administration, Levels of Management & their respective functions, Managerial Skills & roles 1.3. Management Thoughts: Administrative Management Henry Fayol, Scientific Management – Fredrick Taylor, Behavioral approach- Hawthorne's approach, Systems approach, MBO approach	8
2	Unit – II Functions of Management - I 2.1. Planning: Nature, Scope, Objectives of planning 2.2. Process of Planning, Effective Planning-Principles, Planning Premises and Forecasting. 2.3. Organizing: Concept, Designing Organization Structure, and Forms of Organizational Structure, 2.4. Departmentation - need, importance & bases of departmentation 2.5. Case studies on planning and organizing	8
3	Unit III - Management Functions - II 3.1. Staffing: Concept, Manpower Planning, Recent trends in HRM, workforce diversity 3.2. Coordination – Need & Importance, Coordination & Cooperation, Techniques of Effective coordination. 3.3. Decision Making – Types of Decision, decision making processes, Effective Decision, 3.4. Decision making approaches - Problem solving approach, Scientific Approach, Quantitative Approach, Creative Approach 3.5. Case studies on staffing and decision making	8
4	Unit IV - Management Functions - III 4.1. Directing: Concept, principles of directing, supervision 4.2. Controlling: Concept, Types of control, Method: Pre-control - Concurrent control – Post control, Control areas 4.3. Overview of Recent trends in management – Total Quality Management, outsourcing, Learning organization, Business process reengineering, stress management, virtual organizations 4.4. Case studies on directing and controlling	12

5	<p>Unit V - Global Management Practices</p> <p>5.1. Types of Management styles: Comparison between American, Japanese and Indian styles of Management</p> <p>5.2. TOWS matrix: A modern tool for analysis</p> <p>5.3. Diversity and Multiculturalism: Nature, Dimensions, Effects, howto manage Diversity and Multiculturalism in the organization.</p> <p>5.4. Bench Marking- Definition, Need, Levels & prerequisites, Process: Planning, Analysis, Integration, Action Phase, Advantages & limitationsof Benchmarking.</p> <p>5.5. Case studies</p>	6
6	<p>Unit VI - Digital Transformation and Business Models</p> <p>6.1. Overview of Society 5.0</p> <p>6.2. Concept of Digital Transformation</p> <p>6.3. Shifts in Business Models: From Traditional to Platform-Based Models</p> <p>6.4. New Business Models in Industry 4.0- Platform-Based, Subscription-Based, Product-as-a-Service (PaaS)</p> <p>6.5. Challenges and Best Practices in Digital Transformation</p> <p>6.6. Case Studies on Digital Transformation and Business Models</p>	6

REFERENCE BOOKS:

- Essentials of Management - Koontz & Weihrich- McGraw Hill
- Principles of Management – Bhat & Kumar – Oxford University Press
- Management Principles & Application - Griffin, Ricky W. : (Cengage Learning/Thomson Press)
- Principles of Management: Text and Cases, 1e - Bhattacharyya - Pearson
- Global Business Management – Adhikari - Macmillan
- Indian Ethos - Nandagopal Tata McGraw Hill
- Global Management Solutions: Demystified by Seth- Cengage Learning
- Principles Of Management – Neeru Vashisth - Taxmann
- Management - Robbins & Coulter – (Prentice Hall Of India,8th Edition)
- Management : A Global And Entrepreneurial Perspective Weihrich Heinz And KoontzHarold (McGraw Hill 12th Edition 2008)
- Management by Stoner, Freeman, Gilbert – Pearson/ Prentice Hall
- Management: Value-Oriented Holistic Approach by S.A. Sherlekar HimalayaPublishing House

Course 2: Pharmacoeconomics**Total Credits: 04****Lecture Hours: 48 Hours****Course Type: Mandatory DSC****CIE Marks: 40****ESE Marks: 60**

<i>SNo.</i>	<i>Contents of Unit</i>	<i>Hrs</i>
1	Unit – I Introduction to Pharmacoeconomics 2.1 Definition, Need and Scope of Pharmacoeconomics 2.2 Importance of Pharmacoeconomics in Healthcare Decision-Making 2.3 Key Concepts: Cost in Pharmacoeconomics, 2.4 Cost Analysis in Pharmacoeconomics Types of Costs: Direct, Indirect, Intangible, Opportunity cost, Incremental cost, other cost 2.5 Determination of cost of therapy in Pharmacoeconomics study 2.6 Types of cost of services	10
2	Unit-II Pharmacoeconomics Methods 2.5 Cost-Benefit Analysis (CBA) 2.6 Cost-Effectiveness Analysis (CEA) 2.7 Cost of Illness Analysis 2.8 Cost-Minimization Analysis (CMA) 2.9 Cost-Utility Analysis (CUA) 2.10 Budget Impact Analysis 2.11 Applications and Limitations of Each Type	12
3	Unit – III Pharmacoeconomics Modeling 3.1 Introduction to Pharmacoeconomics Models 3.2 Decision analysis and Markov Models 3.3 Sensitivity Analysis and Scenario Planning 3.4 Drug utilization Studies	10
4	Unit – IV Outcome Measurement in Pharmacoeconomics 4.1 Types of Outcome 4.2 Clinical Outcomes: Efficacy, Effectiveness 4.3 Economic Outcomes: Cost Savings, Return on Investment (ROI) 4.4 Humanistic Outcomes: Health Related Quality of Life (HRQoL) 4.5 Patient Satisfaction	6
5	Unit V – Practical Applications of Pharmacoeconomics in the Pharmaceutical Industry 5.1 Pharmacoeconomics in Pharmacotherapy 5.2 Pharmacoeconomics in Drug Approval and Marketing 5.3 Pharmacoeconomics in clinical Practice 5.4 Case Studies: Real-World Applications in Industry Settings	6

REFERENCE BOOKS:

- "Essentials of Pharmacoeconomics" by Karen Rascati
- "Pharmacoeconomics: From Theory to Practice" by Renee J.G. Arnold
- "Health Economics and Outcomes Research: A Practical Guide" by Monica Myles

Course 3: Organizational Behavior

Total Credits: 04

Lecture Hours: 48 Hour

Course Type: Mandatory Course DSC

CIE Marks: 40

ESE Marks: 60

SNo	Contents of Module	Hrs
1	Unit – I Introduction 1.1. Meaning, Nature, Scope, Key elements & Importance of OB 1.2. Various models of OB; Multidisciplinary nature of OB 1.3. Emerging challenges for OB	04
2	Unit – II Foundations of Individual Behavior 2.1. Personality: Concept, Determinants of Personality; Personality Traits influencing behavior; EI and its impact on Personality 2.2. Attitudes: Concept, Types, Components, Functions of Attitudes, Ways to change Attitudes; Attitudes & Behavior 2.3. Perception: Meaning; Perceptual Process; Factors Influencing Perception, Attribution theory; Biases affecting Perception; Perception and OB 2.4. Learning: Meaning; Theories of Learning, Principles of learning: Reinforcement, Punishment and Extinction, Learning & Behavior 2.5. Case Studies	12
3	Unit – III Group Behavior 3.1. Reasons for formation of groups 3.2. Nature & Types of groups 3.3. Stages of Group Development 3.4. Group Properties: Group Norms, Group Size and Group Cohesiveness; Group Think and Group Shift. 3.5. Case Studies	6
4	Unit – IV Interpersonal Relationship 4.1. Nature of Conflict; Functional and Dysfunctional Conflict 4.2. Types of Conflicts: (Individual, Interpersonal & Intergroup) 4.3. Developing interpersonal relations: Transactional Analysis and Johari Window, Conflict Management styles 4.4. Case Studies	6
5	Unit – V Motivation 5.1. Nature & Types of Motivation: Financial & Non-Financial 5.2. Theories of Motivation: 5.2.1. Need Hierarchy Theory 5.2.2. Theory X and Theory Y 5.2.3. Motivation-Hygiene Two Factor theory 5.2.4. ERG theory 5.2.5. Vroom's Expectancy theory 5.2.6. McClelland's Learned Needs Theory 5.3. Case Studies	10
6	Unit – VI Power & Politics 6.1. Concept; Difference between Authority, Power & Leadership 6.2. Sources of Power; Power Tactics 6.3. Organizational Politics; Reasons for Political Behavior 6.4. Political strategies and tactics to acquire power, Managing Political Behavior 6.5. Case Studies	06

7	Unit – VII Work stress 7.1. Concept, Nature and sources of stress of Stress 7.2. Consequences of Stress; Stress & Performance; Stress Management 7.3. Case Studies	04
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REFERENCE BOOKS:

- Organization Behavior 12 e –Fred Luthans - McGraw Hill
- Organization Behavior 15e – Stephen Robbins, Vohra - Pearson
- Organization Behavior – Suja R. Nair, Himalaya Publications
- Organization Behavior –S.S. Khanka – S Chand
- Organization Behavior – V.S.P.Rao – Excel Publication
- Organization Behavior – K. Ashwathappa - Himalaya
- Human Behavior at Work –Keith Devis- Tata McGraw Hill
- Organization Behavior – P. Subba Rao - Himalaya

Course 4 : Business Accounting**Total Credits: 02****Lecture Hours: 24 Hours****Course Type: Mandatory DSC****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Accounting Process 1.1 Accounting Concepts & Conventions 1.2 Double Entry System of Accounting, Types of Accounts 1.3 Journal Entries (Considering GST effect) 1.4 Ledger Posting 1.4 Preparation of Trial Balance Elementary Study of Accounting Standards: As-1, As-2, AS-5, AS-6, AS-10	7
2	Final Accounts 2.1 Proprietor's Final Accounts with Adjustments 2.2 Conceptual Understanding of Financial Statements of Corporate Entities: Share Capital, Reserves and Surplus, Long Term Borrowings, Current Assets, Current Liabilities, Cash & Cash Equivalents 2.3 Contents of Annual Reports of a Company	7
3	Cost Accounting 3.1 Elements of Cost: Direct & Indirect Costs, Fixed & Variable Costs, Factory Overheads, Office & Administration Overheads, Selling & Distribution Overheads. 3.2 Preparation of Cost Sheet 3.3 Items Excluded from Cost Sheet.	6
4	Reconciliation of Cost and Financial Records 4.1 Reconciliation of cost accounting records with financial accounts 4.2 Procedure for reconciliation 4.3 Statement showing reconciliation of profit of Costing & Financial Records	4

REFERENCE BOOKS:

- Fundamentals of Accounting, Dr. P C Tulsian, S. Chand Publications
- Fundamentals of Financial Accounting – Ashok Sehgal – Taxmann
- Fundamentals of Accounting, A K Agrawal and Kamlesh Agrwal, Kitab Mahal
- Costing, by Gangadhar Kayande-Patil, Chaitnya Publications
- Cost Accounting: RSN Pillai, S. Chand Publications

Course 5 : Business Communication**Total Credits: 02****Lecture Hours: 24 Hours****Course Type: Mandatory DSC****CIE Marks: 20****ESE Marks: 30**

SNo	Contents of Module	Hrs
	Unit - I Introduction to Business Communication 1.1 Definition and scope of business communication. 1.2 Importance of communication in the business environment 1.3 Verbal and non-verbal communication. 1.4 Functions of communication.	
2	Unit 2: Communication Strategies 2.1 Developing effective communication strategies. 2.2 Means and Medium of communication 2.3 Barriers to communication 2.4 Internal communication: Employee engagement, Internal newsletters. External communication: Public relations, Press releases.	5
3	Unit 3: Business Writing and Presentation Skills 3.1 Business correspondence: Emails, Memos, Reports. 3.2 Writing skills for business: Clarity, Conciseness, and Tone. 3.3 Presentation skills: Structure, Design, and Delivery. 3.4 Use of visual aids in presentations.	5
4	Unit 4: Digital Communication in Business 4.1 Digital communication channels: Email, Social Media, Websites. 4.2 Content creation and management: Blogs, Videos, Podcasts. 4.3 SEO and content distribution strategies. 4.4 Ethical considerations in digital communication.	5

REFERENCE BOOKS:

- Lesikar R/ Flatley M. (9th ed). Basic Business Communication: Skills For Empowering The Internet Generation. TMH.
- Bedi R/ Aruna K. (1st ed). Business Communication. Vrinda.
- Kaul Asha. Business Communication. PHI.
- Rai U./ Rai S. M (10th). Business Communication. Himalaya.
- Sinha K. K. Business Communication. Galgotia.
- Sharma R. C/ Mohan K. (3rd ed). Business Correspondence & Report Writing. TMH.

Course 6 : AI Basics for Managers**Total Credits: 02****Lecture Hours: 24 Hours****Course Type: Mandatory DSC****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit 1: Introduction to Artificial Intelligence 1.1 AI Definitions and Key Concepts 1.2 History and Evolution of AI 1.3 Types of AI: Narrow AI vs. General AI 1.4 Core AI Technologies: Machine Learning, Natural Language 1.5 Processing, Computer Vision 1.6 Real-World Applications of AI in Business 1.7 AI Myths and Realities	12
2	Unit 2: Understanding Machine Learning and Data 2.1 Basics of Machine Learning: Supervised, Unsupervised, and Reinforcement Learning 2.3 Data's Role in AI: Types of Data, Data Quality, and Data Management 2.4 Introduction to Algorithms: How Machines Learn from Data 2.5 Understanding Predictive Analytics 2.6 Key Tools and Platforms for Machine Learning	6
3	Unit - III AI Strategy and Implementation 3.1 Building an AI Strategy: Aligning AI with Business Goals 3.2 AI in Decision-Making: Enhancing Business Intelligence 3.3 Integrating AI into Existing Systems and Processes 3.4 Managing AI Projects: Key Steps and Considerations	6
4	Unit 4: Ethics, Governance, and the Future of AI 4.1 Ethical AI: Bias, Transparency, and Fairness 4.2 AI Governance: Policies, Regulations, and Compliance 4.3 The Impact of AI on Jobs and the Workforce 4.4 AI and the Future of Business: Emerging Trends and Innovations	6

REFERENCE BOOKS:

- "Artificial Intelligence: A Guide for Thinking Humans" by Melanie Mitchell
- "Prediction Machines: The Simple Economics of Artificial Intelligence" by Ajay Agrawal, Joshua Gans, and Avi Goldfarb
- "Competing in the Age of AI" by Marco Iansiti and Karim R. Lakhani
- "Human + Machine: Reimagining Work in the Age of AI" by Paul R. Daugherty and H. James Wilson

Course 7: General Pharmacology & Pharmacoepidemiology

Total Credits: 4

Lecture Hours: 48 Hours

Course Type: Elective course DSC

CIE Marks: 40

ESE Marks: 60

SNo	Contents of Unit	Hrs
1	Unit - I Introduction to General Pharmacology 1.1 Overview of Pharmacology and Its Role in Healthcare 1.2 Drug-Receptor Interactions: Agonists, Antagonists, and Receptor Theory 1.3 Pharmacokinetics: Absorption, Distribution, Metabolism, and Excretion (ADME) 1.4 Pharmacodynamics: Dose-Response Relationships, Therapeutic Index, and Drug Efficacy 1.5 Factors Influencing Drug Action: Age, Gender, Genetics, and Disease States	6
2	Unit-II Pharmacokinetics and Pharmacodynamics 2.1 Mechanisms of Drug Absorption and Bioavailability 2.2 Drug Distribution and Factors Affecting Distribution Metabolism of Drugs: Phase I and Phase II Reactions 2.3 Excretion of Drugs: Renal and Non-Renal Pathways 2.4 Concept of Pharmacokinetic-Pharmacodynamics and Its Applications	10
3	Unit - III Introduction to Pharmacoepidemiology 3.1 Definition and Scope of Pharmacoepidemiology 3.2 Measurement of outcomes in pharmacoepidemiology 3.3 Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, Medication adherence measurement 3.4 Concept of risk in pharmacoepidemiology: Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio	12
4	Unit IV-Methods for Pharmacoepidemiologic Studies 4.1 Various methods and practical study with the help of case studies for individual methods 4.2 Drug utilization review, case reports, case series, surveys of drug use, cross - sectional studies, cohort studies, case control studies, case -cohort studies, meta - analysis studies, spontaneous reporting, prescription event monitoring and record linkage system. 4.3 Drug Safety and Pharmacovigilance: Introduction to Pharmacovigilance 4.4 Adverse Drug Reactions (ADRs): Classification, Detection, and Reporting	10
5	Unit V - Pharmacoepidemiology and Public Health 5.1 Role of Regulatory Agencies in Drug Safety: FDA, EMA, and WHO 5.2 Assessing the Burden of Disease and Drug-Related Morbidity and Mortality 5.3 Pharmacoepidemiology in Drug Policy and Healthcare Decision-Making	6

6	Unit VI: Ethical and Regulatory Considerations in Pharmacoepidemiology 6.1 Role of Ethics Committees and Institutional Review Boards (IRBs) 6.2 Ethical Issues in Pharmacoepidemiological Research: Informed Consent, Confidentiality, and Data Protection 6.3 Regulatory Frameworks Governing Pharmacoepidemiology: International Guidelines and Best Practices 6.4 Case Study in Pharmacoepidemiology	4
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REFERENCE BOOKS:

- "Goodman & Gilman's: The Pharmacological Basis of Therapeutics" by Laurence L. Brunton
- "Pharmacoepidemiology" by Brian L. Strom
- "Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy" by David E. Golan

Course 8: Operations Management**Total Credits: 04****Lecture Hours: 48 Hours****Course Type: Elective Course****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit - I Introduction to Operation Management 1.1 Definition, production functions & Responsibilities of Production 1.2 Management and its relations to other management functions, 1.3 Automation. Difference between services and Manufacturing. 1.4 Competitiveness Strategy and productivity. Computing productivity	6
2	Unit - II Product & Service Design 2.1 Objectives, legal and Environmental issues, Lifecycles 2.2 Standardization, Mass customization Delayed Differentiation. 2.3 Modular design, Reliability, Improving reliability. 2.4 Phases in product design and development. 2.5 Design for manufacturing, concurrent Engineering, CAD, and Recycling Component Commonality. 2.6 Service Design, Difference between product design and service design	8
3	Unit - III Capacity Planning & Facility Layout 3.1 Defining & measuring capacity, determinants of effective capacity. 3.2 Determining capacity requirements, make or buy decisions. 3.3 Developing capacity alternatives. Challenges of planning service capacity. CVP Analysis 3.4 Facilities layout, repetitive product and process layouts. Fixed position layout, combination layout, 3.5 Cellular layout, Group technology, other service layouts, designing product layouts. 3.6 Production planning and control - Routing, sequencing, loading, scheduling, master scheduling	12
4	Unit - IV Quality Assurance & Inventory Management 4.1 Inspection, Statistical process control, Control charts, acceptance sampling concept, risks, cost of quality control; 4.2 ISO Quality Systems: ISO:9000, ISO:14000, Total Quality Control - concept, KAIZEN, six sigma concept. 4.3 Nature and importance of Inventory, Functions and Objectives. 4.4 Requirements for effective Inventory Management, Inventory costs 4.5 Inventory Classification System, ABC Analysis, EOQ Models, Economic Production Quantity Model	8
5	Unit - V Supply Chain Management 5.1. Definition, Importance, Strategy & drivers of supply chain. 5.2 Logistics: functions, objectives, solution, Customer Service, Warehousing and Material, Storage, Material Handling, Transportation and Packaging. Distribution - Network Design, Role, Factors Influencing, Options, Value Additions, Impact of uncertainty on Network Design, Network Design decisions using Decision trees. 5.3 E-Business: Framework and Role of Supply Chain in e- business and b2b practices, Supply Chain IT Framework	6

REFERENCE BOOKS:

- Production and Operations Management–K. Ashwathappa and K. Shridhar Bhat-Himalaya Publishing
- Everest E Adam & Albert, Productions and Operations Management, IVth Ed, PHI Publications.
- Mohanty R. P. and S. G. Deshmukh, Advanced operations management, Pearson Education, First Edition.
- Altekar Rahul V, Supply Chain Management-Concept and Cases, Prentice Hall
- India,2005.
- Production & Operation Management Second Edition – Kanishka Bedi - Oxford

Course 9: Research Methodology**Total Credits: 04****Lecture Hours: 48 Hours****Course Type: Mandatory DSC****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit – I Basics of Research Methodology 1.1. Meaning, Objective & Types of Research, 1.2. Research Process 1.3. Managerial Value of Business Research 1.4. Literature Survey	12
2	Unit – II Formulation of Research Problem 2.1 Research Problem: Importance of Formulation, Sources, Considerations in selecting research Problem, steps in formulation, Factors of Problem Identification 2.2 Formulation of Objectives, 2.3 Establishing operational definition, 2.4 Variable- Concept Vs Variable, types/classification, construct 2.5 Scale characteristic, Measurement Scales: Nominal, Ordinal, Interval, Ratio 2.6 Hypothesis: Meaning, Functions, Characteristic, Sources & Types of Hypothesis,	12
3	Unit – II Research Design & Sampling Design 3.1 Research Design: Meaning, Types & Feature of Research Design, Factors Affecting Research Design 3.2 Sampling Design: Sample, Sampling, Steps, Criterion of selecting sampling procedure, 3.3 Sampling Methods: Probability Sampling, Non-probability Sampling	6
4	Unit – IV Data Collection 4.1 Types & Sources of Data: Primary & Secondary data, Methods of Primary Data Collection: Observation, Interview, Questionnaire, Schedule, Schedule vs Questionnaire, Wording Questions, guidelines for constructing questions. 4.2 Criterion for good Measurement: Validity, Reliability, Sensitivity 4.3 Scaling Techniques: Rating Scales, Ranking Scales. 4.4 Factors in selecting appropriate measurement scale 4.5 Qualitative research: Meaning, uses of qualitative research, Qualitative vs Quantitative research, Orientations: Phenomenology, Ethnography, Grounded theory, Case studies.	8
5	Unit – V Testing of Hypotheses 5.1 Basic Concept Concerning Testing of Hypotheses, Procedure for Hypotheses Testing 5.2 Advanced Tools for Hypothesis Testing Using SPSS: 5.3 Introduction to SPSS package, creating data files 5.4 Multiple Response sets, Recoding, visual binning etc. 5.5 Frequencies, Descriptive statistics, Chi square analysis & Cross Tabulation 5.6 Reliability Analysis: Cronbach alpha, One sample t-test, Independent sample t-test, Linear Correlation & Regression, One Way Analysis of Variance (ANOVA) 5.7 Multivariate Data Analysis: Factor Analysis	6

6	Unit – VI Interpretation & Report Writing 6.1 Interpretation: Meaning, Techniques, 6.2 Effective use of graphic aid: Tables, charts, pie charts, line graphs, bar charts, 6.3 Research Outline/proposal, 6.4 Research report writing,	4
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REFERENCE BOOKS:

- Business Research Methods- Donald R. Cooper, Schindler, Sharma – 11th Edition - McGraw-Hill
- Business Research Methods: A South Asian Perspective-8th Edition - Zikmund, Adhikari – Cengage
- Management Research Methodology – Krishnaswamy, Sivakumar, Mathirajan– Pearson Education
- Research Methodology- Prashant Sarangi –Taxmann Publications
- Research Methodology: a step-by-step guide for beginners - Ranjit Kumar - Sage
- Research Methodology (Methods & Techniques) – C.R.Kothari – New age
- Doing Data Analysis with SPSS by Carver, Nash – BROOKS/COLE Cengage Learning

SEMESTER II

Course 1: Drug Regulatory Affairs**Total Credits: 04****Lecture Hours: 48 Hours****Course Type: Mandatory course DSC****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Unit	Hrs
1	Unit – I Introduction to Drug Regulatory Affairs 1.1 Overview of Drug Regulatory Affairs 1.2 Importance of Regulatory Compliance in the Pharmaceutical Industry 1.3 Key Regulatory Bodies: FDA (USA), EMA (Europe), CDSCO (India), MHRA (UK), TGA (Australia), etc. 1.4 Regulatory Affairs as a Strategic Function in Pharmaceutical Management	6
2	Unit-II Drug Development and Approval Process 2.1 Drug Development Lifecycle: Discovery, Preclinical, Clinical Trials, and Post-Approval 2.2 Investigational New Drug (IND) Application and New Drug Application (NDA) 2.3 Marketing Authorization Applications (MAA) and Abbreviated New Drug Applications (ANDA) 2.4 Preclinical and Clinical Trials Regulations and Good Clinical Practice (GCP) 2.5 Case Study: The Drug Approval Process for a New Drug	10
3	Unit –III Key Regulations and Guidelines 3.1 Overview of Major Regulations: ICH Guidelines, 21 CFR (FDA), EU Directives, Schedule Y (India) 3.2 Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Distribution Practice (GDP) 3.3 Pharmacovigilance Regulations and Adverse Event Reporting 3.4 Labelling, Packaging, and Advertising Regulations Case Study: Regulatory Challenges in Drug Labelling and Advertising	14
4	Unit – IV Regulatory Documentation and Submission 4.1 Preparation of Regulatory Dossiers: Common Technical Document (CTD) Format 4.2 Electronic Submission Standards: eCTD and eSubmission 4.3 Regulatory Strategies for Global Drug Development 4.4 Role of Regulatory Affairs Professionals in Drug Registration and Licensing	10
5	Unit V – Post-Marketing Surveillance and Compliance 5.1 Post-Marketing Surveillance: Pharmacovigilance and Risk Management 5.2 Adverse Drug Reaction (ADR) Monitoring and Reporting 5.8 Regulatory Affairs in Drug Recalls and Withdrawals 5.9 Case Study: Post-Marketing Surveillance and the Role of Regulatory Affairs	8

REFERENCE BOOKS

- "Drug Regulatory Affairs" by Gajendra Singh
- "Intellectual Property Rights and Drug Regulatory Affairs" by Dr. Ruchi Tiwari and Dr.Gaurav Tiwari
- "Fundamentals of US Regulatory Affairs" by RAPS (Regulatory Affairs Professionals Society)
- "Drug Regulatory Affairs" by Sachin Itkar and P. P. Sharma "Pharmaceutical Regulatory Affairs: An Overview" by Lisa A. English

Course 2 : Indian Economy and Policies Course Type: mandatory Course DSC
Total Credits: 02 CIE Marks: 20
Lecture Hours: 24 Hours ESE Marks: 30

SNo	Contents of Module	Hrs
1.	Unit – I Economic Indicators and Economic Growth and Development 1.1. Circular Flow of Income 1.2. National Income Accounting – Terms and Concepts 1.3. Three Methods of measuring GDP/GNP 1.4. Meaning of Economic Growth and Development 1.5. Measuring Economic development 1.6. Determinants of Economic Development	6
2.	Unit – II Indian Economy- Structure, features and Issues 2.1 Indian Economy – Basic Structure 2.2 Features of Indian Economy 2.3 Structural changes in Indian Economy 2.4 Trends in National Income 2.5 Pattern of Income Distribution in India 2.6 Indian Economy and related to planning, issues Related to Growth and Development, Unemployment issues	6
3.	Unit – III Indian Economy and Macro Economic Policies 3.5 Introduction to macroeconomic- Equilibrium in the economy, Concepts of Inflation and Deflation 3.6 Monetary policy– Meaning, Objectives, Instruments. 3.7 Fiscal Policy –Meaning and Objectives 3.8 Exchange rate policies and Foreign Trade Policy 3.9 Public Sector and Private Sector in Economy – Rationale and Critiques of Privatization	6
4.	Unit – IV Globalization and Indian Economy 4.1 Balance of Payment and its protectionism – Concept & Components of BOP – India’s BOP Situation 4.2 Globalization- Meaning, Dimensions of Globalization, Strategies of Globalization 4.3 Globalization and its impact on Indian Economy 4.4 World Trade Organization (WTO), India and WTO	6

REFERENCE BOOKS:

- Indian Economy – V.K. Puri; S.K. Mishra – Himalaya Publishing House
- Indian Economy – A.N. Agrawal – New Age International Publishers
- Indian Economy – Ruddar Datt & KPM Sundharam – S.Chand Publishers
- Indian Economy – Gaurav Datt & Ashwani Mahajan-- S.Chand Publishers
- Indian Economy – Ramesh Singh – Tata Mcgraw Hill
- Indian Economy – Nitin Singhania – Tata Mcgraw Hill
- Indian Economy – Sriram Srirangam; Manish Kumar; Rohit Deo Jha – Pearson

Course 3:Human Resource Management Course Type: Mandatory course

Total Credits: 04

CIE Marks: 40

Lecture Hours: 48 Hours

ESE Marks: 60

SNo	Contents of Module	Hrs
1	Unit – I Introduction to Human Resource Management (HRM) 1.1. Concept, Nature, Scope, Objectives & Functions of HRM, 1.2. HRM Vs. HRD, HRM Environment, 1.3. HR's Changing Role 1.4. Role & Qualities of HR Manager 1.5. Future Role & Challenges before HRM	6
2	Unit – II Process of Procurement 2.1 Human Resource Planning: Concept, Need of HRP, 2.2 Factors Affecting HRP Process of Human Resource Planning – forecasting HR Requirement and availability, 2.3 Uses of HR database, Shortage & Surplus of workers forecasted, Downsizing. 2.4 Recruitment: Concept, Purpose & Factors Affecting Recruitment, Sources & Process of Recruitment 2.5 Selection: Concept, Selection process, Selection tests, barriers of selection 2.6 Placement: Concept & Problems 2.7 Induction/Orientation: Concept, Objective, Steps & Problems in Orientation, Topics of Induction Programme, Onboarding 2.8 Concept of Promotion, Types of promotion, Purpose of Promotion, Principles of Promotion 2.9 Meaning of Demotion, Reasons, and Principles of Demotion 2.10 Meaning and Types of Transfer, Reasons, and Principles of Transfer.Layoff, Rightsizing, VRS	12
3	Unit – III Career & Succession Planning 3.1. Career Planning: Meaning, Need, features, objective of career Planning, Process of career planning, Career Guidance, Career Stages 3.2. Career Development: Roles in career Development, Career Development Initiatives 3.3. Succession Planning: Meaning, Process & Benefits of Succession Planning	6
4	Unit – IV Performance appraisal 4.1. Definitions, Objective 4.2. Process & Methods of Performance Appraisal: Traditional Methods, Modern Methods, 4.3. Problems with Performance Appraisal 4.4. Competency Mapping: Concept, Need, Competencies Applications, Classifying Competencies	8
5	Unit – V Employee Training & Executive Development 5.1. Meaning, Need and Objective of Training & Development 5.2. The Training procedure 5.3. Difference between Training & Development, 5.4. Methods of Training & Development: On the Job & Off the Job, Evaluation of Training	8

6	Unit – VI Other Practices 6.1. Concept of VUCA, Human Resource Information System, Moonlighting by employees, 6.2. Work Life Balance, Employee Engagement, Employer branding, Attrition & Retention, 6.3. Emotional Intelligence, Flexi-time & Flexi-work, Counselling, coaching & Mentoring, 6.4. CTC (Cost to Company) , Employee Stock Ownership Plan (ESOP), E-HRM.	8
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REFERENCE BOOKS:

- Human Resource Management: A south Asian Perspective – Mathis, Jackson, Tripathi – Cengage
- Human Resource Management by Wayne Mondy – Pearson
- Human Resource Management, Text & Cases By Dr. V.S.P Rao - Excel Books
- Human Resource Management: A south Asian Perspective By Snell, Bohalender, Vohra- Cengage
- Human Resource Management By Dr K. Ashwathappa – Tata McGraw Hill
- Personnel and Human Resource Management by P. Subba Rao – Himalaya Publishing House
- Human Resource Management, Text and Cases by Dr. S.S. Khanka- S. Chand
- Human Resource Management by Haladkar& Sarkar – Oxford University Press
- Human Resource Management By Dr. Shikha Kapoor – Taxmann
- Essentials of Human Resource Management By P. SubbaRao – Himalaya Publishing House

Course 4: Pharmaceutical Marketing Management

Total Credits: 02

Lecture Hours: 48 Hours

Course Type: Mandatory course DSC

CIE Marks: 40

ESE Marks: 60

SNo	Contents of Unit	Hrs
1	UNIT 1: Introduction to Pharmaceutical Marketing 1.1 Overview of Pharmaceutical Marketing and its Importance 1.2 Marketing Concepts and Theories in the Pharmaceutical Context 1.3 The Pharmaceutical Market Environment: Trends and Challenges Industry and competitive analysis 1.4 The Role of Marketing in Pharmaceutical Business Strategy	6
2	UNIT 2: Market Analysis and Consumer Behavior 2.1 Market Research in the Pharmaceutical Industry 2.3 Understanding Consumer Behavior in Pharmaceuticals: Patients, Physicians, and Pharmacists, Industrial Buying Behaviour 2.4 Market Segmentation, Targeting, and Positioning Strategies Competitive Analysis in the Pharmaceutical Industry	8
3	UNIT 3: Product Life Cycle Management 3.3 New Product Development in Pharmaceuticals 3.4 Managing the Product Life Cycle: Strategies for Each Stage 3.5 Product Portfolio Management, Product positioning, New product decision, packaging and labelling decision, Product Management in pharmaceutical industry. 3.6 Case Study: Successful Product Life Cycle Management in Pharma	8
4	UNIT 4: Branding and Product Differentiation 4.1 Building Strong Pharmaceutical Brands 4.2 Strategies for Product Differentiation in a Competitive Market 4.3 Brand Equity and Brand Management	8
5	UNIT 5: Pricing Strategies in Pharmaceuticals 5.1 Meaning, Importance, objectives, Factors Influencing Pricing Decisions in the Pharmaceutical Industry 5.2 An overview of DPC (Drug Price control order) and NPPA (National Pharmaceutical pricing authority) 5.2 Pricing Models: Cost-Based, Value-Based, and Competition-Based Pricing 5.3 The Impact of Government Regulations on Pricing Case Study: Pricing Strategies in Different Market Conditions	8
6	UNIT 6: Distribution Channels and Supply Chain Management 6.1 Distribution Strategies for Pharmaceutical Products 6.2 Role of Wholesalers, Retailers, and Online Platforms 6.3 Managing the Pharmaceutical Supply Chain for Market Efficiency 6.4 The Promotional Mix in Pharmaceutical Marketing: Advertising, Sales 6.5 Promotion, Public Relations, and Personal Selling 6.6 Direct-to-Consumer (DTC) Advertising and its Impact 6.7 Digital Marketing and Social Media Strategies in Pharmaceuticals 6.8 Regulatory and Ethical Issues in Pharmaceutical Promotion 6.9 Innovative Promotional Strategies in Pharma	10

REFERENCE BOOKS:

- "Pharmaceutical Marketing" by Mickey C. Smith
- "Pharmaceutical Marketing: Strategy and Cases" by Subba Rao Chaganti
- "Essentials of Pharmaceutical Marketing" by D.M. Vasudevan and Sreekumari S

Course 5: Financial Management**Total Credits: 04****Lecture Hours: 48 hrs****Course Type: Mandatory Course DSC****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit – I Financial Management 1.1 Meaning, Nature, Scope and Objectives 1.2 Traditional & Modern Approaches 1.3 Functional areas of finance 1.4 Financial Forecasting 1.5 Few Concepts of finance: 1.5.1. Time value of Money, Concept of risk & return 1.5.2. Interest Rates: Nominal Interest Rate, Real Interest Rate 1.5.3. Measuring shareholders Value Creation: Economic value Added	8
2	Unit – II Finance for Planning & control 2.1. Budget & Budgetary Control 2.1.1. Concept, Objectives, & Limitations 2.1.2. Classification of Budgets – Operating, Financial & Capital Budget 2.1.3. Cash Budget, Flexible budget 2.2. Standard Costing 2.2.1. Concept, Essentials of an effective system of standard costing 2.2.2. Calculation of Material Variances 2.2.3. Calculation of Labor Variances 2.2.4. Causes & Disposition of the variances	8
3	Unit - III Analysis & Interpretation of Financial Statements 3.1 Techniques of financial Statement Analysis: Comparative Financial Statements, Common Size Statement, Trend Analysis, Ratio Analysis 3.2 Ratio Analysis: Liquidity Ratios, Activity Ratios, Profitability Ratios, Solvency Ratios 3.3 Limitations of Ratio Analysis	6
4	Unit – IV Funds flow & Cash Flow Analysis 4.1 Concept of Funds, Funds from Operations 4.2 Statement of changes in working capital, Funds Flow Statement 4.3 Preparation of Cash flow statement (Refer AS-3)	8
5	Unit – V Marginal Costing & Break-Even Analysis 5.1 Concept of Marginal Cost: Contribution, Variable Cost, Fixed Cost, Semi-Variable Cost 5.2 Margin of Safety, PV Ratio 5.3 Assumptions of Break-Even Analysis & Calculations of Break-Even Point	8
6	Unit – VI Management of Working Capital 6.1 Concepts: Gross and Net, Permanent & Temporary, Operating Cycle 6.2 Disadvantages of insufficient Working Capital 6.3 Financing of Working Capital, Maximum Permissible Bank finance 6.4 Factors Determining Working Capital Requirement 6.5 Estimation of Working Capital Requirement	8

REFERENCE BOOKS:

- Financial Management: Dr. R P Rustagi, Taxmann Publications
- Financial Management by Shrivastava & Mishra- Oxford University Press
- Accounting for Management by Ramanathan- Oxford
- Financial Accounting for Management by Ramachandran& Kakani- McGraw Hill
- Management Accounting: Khan & Jain , Tata Mc-Graw Hill
- Financial Management: Ravi Kishore, Taxmann Publications
- Management Accounting: I. M. Pandey, Vikas Publication

Course 6 : Pharmaceutical Industry Ethics**Course Type: Mandatory****Couse DSC****Total Credits: 02****CIE Marks: 20****Lecture Hours: 24 Hours****ESE Marks: 30**

SNo	Contents of Unit	Hrs
1	UNIT 1: Introduction to Pharmaceutical Ethics 1.1 Overview of Ethics in Business: Definitions, importance, and role of ethics in the pharmaceutical industry. 1.2 Ethical Theories and Frameworks: Utilitarianism, deontology, virtue ethics, and their relevance to pharmaceutical practices. 1.3 The Importance of Ethics in Pharmaceuticals: Public trust, industry reputation, and the consequences of unethical behavior. Code of Pharmaceutical Ethics	6
2	UNIT 2: Regulatory and Legal Frameworks 2.2 Global Regulatory Bodies: FDA, EMA, WHO, and their role in enforcing ethical standards. 2.3 Key Regulations: Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Distribution Practice (GDP), and their ethical implications. 2.4 Compliance and Ethics: The role of compliance programs in upholding ethical standards, whistleblowing, and corporate governance.	6
3	UNIT 3: Ethical Issues in Drug Development and Marketing 3.1 Pre-clinical & Clinical Trials Ethics: CPCSEA's principal for animal use, Informed consent, patient safety, placebo use, and the role of Institutional Review Boards (IRBs). 3.2 Drug Pricing and Accessibility: Ethical considerations in pricing strategies, access to essential medicines, and affordability. 3.3 Marketing and Advertising Ethics: Ethical concerns in drug promotion, direct-to-consumer advertising, and transparency in communication.	5
4	UNIT 4: Corporate Social Responsibility (CSR) in Pharmaceuticals 4.1 CSR and Sustainability: The role of CSR in promoting ethical practices, sustainability, and environmental responsibility. 4.2 Philanthropy and Global Health: Pharmaceutical contributions to global health initiatives, ethical issues in drug donations, and access to medicines in developing countries. 4.3 Ethical Leadership in Pharmaceuticals: The role of leadership in fostering an ethical culture, case studies of ethical leadership in the industry Case Studies in Pharmaceutical Ethics 4.4 Historical Case Studies: Analysis of major ethical violations in the industry (e.g., Thalidomide, Vioxx, Opioid Crisis). 4.5 Contemporary Ethical Challenges: Current ethical dilemmas, such as vaccine equity during pandemics, drug shortages, and patent controversies. 4.6 Scenario-Based Learning: Applying ethical frameworks to hypothetical scenarios and real-world cases in pharmaceutical management.	7

REFERENCE BOOKS:

- Pharmaceutical Ethics by Sam Salek and Stuart R. Walker
- Ethics and the Pharmaceutical Industry by Michael A. Santoro and Thomas M. Gorrie
- Pharmaceutical Marketing: Principles, Environment, and Practice by Brent L. Rollins and Matthew Perri III
- The Ethics of Pharmaceutical Industry Influence in Medicine by Sergio Sismondo and Jeremy A. Greene
- Relevant articles from journals like Journal of Medical Ethics and Pharmaceutical Policy and Law

Course 7: Entrepreneurship & Start-up Ecosystem Course Type:**Elective Course****Total Credits: 04****CIE Marks: 40****Lecture Hours: 48 Hours****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit I – Entrepreneurial Management 1.1 Entrepreneurship & its Evolution 1.2 Role of entrepreneur 1.3 Idea Generation, Screening, Selection & Managing Resources. 1.4 Leading & building a team in Enterprise 1.5 Strategic planning of Business. Business plan - meaning, significance and contents – Formulation & presentation – common errors – Preparation of project report.	8
2	Unit II - Entrepreneurship & Creativity 2.1 Entrepreneurship: Role of stimulating creativity 2.2 Creativity & Entrepreneurship, Steps in creativity. Creativity Problem solving – brainstorming, Gordon model, checklist method, Free Association & Big dream approach. 2.4 Decision making & problem solving- steps in decision making. 2.5 Developing business model.	8
3	Unit III- Emerging trends in entrepreneurship development 3.1 Digital entrepreneurship - Meaning, scope and opportunities. Social entrepreneurship – Meaning, Supporting and Evaluating Social Entrepreneurship in India. Sustainable entrepreneurship – Meaning, types, factors, characteristics. Inclusive entrepreneurship – Meaning, Impact on economic growth, support networks fostering success for inclusive Entrepreneurs. 3.5 Case Study on Emerging trends in entrepreneurship development	8
4	Unit IV – Start up ecosystem Overview 4.1 Start-up Opportunities – The New Industrial Revolution, The Big idea- Generate ideas with brainstorming, Ideation- Venture choices. 4.2 The rise of start-up economy, The six forces of change. 4.3 Identifying start-up capital resource requirements. 4.4 Develop financial Assumption- startup financial Metrics The legal environment – Approval for new venture, Taxes or duties payable for Ventures.	8
5	Unit V – Startup Management 1 Sources of Financing - Personal financing, Debt or Equity Financing, Business Angels, Venture Capital, Initial Public Offering, Commercial Banks, Other Sources of Debt Financing, Leasing. 2 Building & Scaling start-ups – Strategies for building strong team, Product development, Go to market strategies, growth & sustainability. 5.3 Start-up Ecosystem in India 5.4 Developing a sustainable business model. 5.5 Case study	8

	Unit – VI Introduction to Family Business	
6	4.1 Defining family business, Distinction between family & non family business. 4.2 Circle models of family influence, Advantages & disadvantages. 4.3 The system theory model of family business. 4.4 Agency Theory of Family Business. 4.5 The Stewardship Perspective of Family Business	8

REFERENCE BOOKS:

- Entrepreneurship Development small business Enterprises, Poornima Charantimath – Pearson.
- Entrepreneurship, Robert D. Hisrich, Michal P. Peters, Tata McGraw-Hill Edition Entrepreneurship: Creating and Leading an Entrepreneurial Organization – Arya Kumar – Pearson.
- Steven Fisher, Ja-nae’ Duane, The Startup Equation -A Visual Guidebook for Building Your Startup, Indian Edition, Mc Graw Hill Education India Pvt. Ltd, 2016.
- Managing the Family Business: Theory and Practice, Thomas Zellweger - Elgar

Course 8 : Sustainability Development**Total Credits: 04****Lecture Hours: 48 Hours****Course Type: Elective Course****CIE Marks: 40****ESE Marks: 60**

SNo	Contents of Module	Hrs
1	Unit – I Basics of Sustainability Management 1.1 Introduction to sustainability, and sustainable development. Concepts of sustainability and sustainable development. 1.2 Technology; concepts and definitions. 1.3 Components of sustainability (Social, Economic, Environmental). 1.4 Linkages between resource use, technology, and sustainability. 1.5 Interactions between energy and technology, and their implications for environment and sustainable development. 1.6 Measuring and Benchmarking Sustainability - Sustainability proofing; Frameworks for measuring sustainability; Indicators of sustainability. 1.7 Sustainability Transitions, Drivers and Barriers; Policy and Institutional Innovations. Sustainability transition Case Studies.	12
2	Unit – II Design & technology in Sustainability 2.1 Understand, evaluate, define, and forecast sustainability. 2.2 Understanding of technology/design and detailed analysis of each chosen design/technology 2.3 Development of technology/design-integrated systems model 2.4 Consideration of 17 Sustainable Development Goals (SDGs) 2.5 Coverage of the fundamental mandate of SDG-4 2.6 Addressing feasibility, opportunities, challenges, and limitations in achieving sustainability.	6
3	Unit – III Air Pollution, Meteorological Aspects of Air Pollutant Dispersion 3.1 Definition, Scales of Concentration, emission sources Air pollution law 3.2 Standards Temperature, lapse rates and Stability 3.3 Plume Behavior and Dispersion of Air pollutants Air pollution control methods	6
4	Unit – IV Low Carbon Infrastructure 4.1 Climate and building design 4.2 Green Building concepts 4.3 Building energy efficiency and renewable energy assessment in buildings Indoor air quality and wellness 4.4 Sustainable construction and maintainability 4.5 Low-carbon material and process	6
5	Unit – V Wastewater sampling, analysis and treatment 5.1 Sampling, methods of Sampling 5.2 Determination of Organic and Inorganic matter/substance 5.3 Bacteriological measurements and Water quality standards 5.4 Basic process of water treatment and Primary treatment 5.5 Secondary treatment 5.6 Advanced waste water treatment	8

6.	Unit – VI Solid Waste Management 6.1 Sources and Classification 6.2 Public health aspects 6.3 Methods of collection and Disposal Recovery and recycling	4
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REFERENCE BOOKS:

- An Introduction to Sustainable Development- Peter P Rogers, Kazi Jalal, John A Byod – Earth scan
- Sustainable Development Goals –Julia Walker, Alma Pelmezovic, Gordon Walker – John Wiley and Sons Limited
- Environmental Pollution Control engineering- CS Rao- 2e- New Age International Publishers
- Sustainability Management – Dr. Deb Prasanna Choudhury–Zorba Books Pvt. Ltd.
- Environmental Management towards sustainability- Prasad Modak- 2018- CRC Press

Course 9 : SWAYAM/NPTEL/ MOOC

Total Credits: 04

Lecture Hours: 48 (12/ 16 Week)

Course Type: Elective Course

CIE Marks: NA

ESE Marks: 100

Course 10 : Field Project

Total Credits: 02

Lecture Hours: 24 Hours

Course Type: Mandatory course

CIE Marks: 20

ESE Marks: 30

Course 11: Internship

Total Credits : 04

Total Hours: 50hrs

Course type: mandatory Course

CIE MARKS : NA

ESE Marks : 50

Evaluation of Field Project:

The Field Project Report shall be evaluated on the basis of Conduct of Viva-voce of **50 Marks**

1. In the course of Viva-voce, the questions may be asked on selection of topic, importance/ relevance of the study, objective of the study, methodology adopted/ Key learning/takeaways/ skills acquired: **15 Marks**
2. Assess the students ability to explain the study outcome of the Field project: **20 Marks**
3. Overall Impression (including Communication Skill): **15 Marks**

Evaluation of Internship:

The Internship Report shall be evaluated on the basis of Conduct of Viva-voce and certification for **50 Marks**

Criteria	Average 0-60% Marks	Admirable 61-90% Marks	Outstanding 91-100% Marks
Topic Selection Objectives & Research Methodology (5)	<ul style="list-style-type: none"> • Topic is acceptable • Description of how the data was collected` what/howmany data sources were analyzed, plan of analysis or measurement instrument, research context is somewhat confusing/not clearly articulated. 	<ul style="list-style-type: none"> • Topic is Clear and precise • Description of how the data was collected, what/howmany data sources were analyzed, plan of analysis or measurement instrument, research context is adequate but limited. 	<ul style="list-style-type: none"> • Topic is Appropriate • Objectives are Clearly defined • Provides accurate, description of how the data was collected, what/howmany data sources were analyzed, plan of analysis or measurement instrument, research context
Theoretical Background & Literature Review (10)	<ul style="list-style-type: none"> • Minimal discussionof research focus/purpose of research • Research focus is not well-grounded in previous research /theoretically relevant literature 	<ul style="list-style-type: none"> • Limited discussionof research focus/purpose of research • Research focus is less well-grounded in previous research /theoretically relevant literature 	<ul style="list-style-type: none"> • Clearly identifies and discusses research focus/purpose of research • Research focus is clearly grounded in previous research/ theoretically relevant literature
Data Analysis& Findings (20)	<ul style="list-style-type: none"> • Results are not very clearly explained, level of detail is insufficient, and there are more organizational issues • Tables/figures are not clear / concise in conveying the data. • Statistical analyses(if used) are inappropriate tests and/or are not accurately interpreted. • Suggestions for further research 	<ul style="list-style-type: none"> • Results are explained but not asclearly, level of detail is not as sufficient, and thereare some organizational issues • Tables/figures are not as clear / concise in conveying the data. • Statistical analyses(if used) are appropriate tests but are not accurately interpreted. • Suggestions for further research in this area are 	<ul style="list-style-type: none"> • Results are clearly explained in a comprehensive level of detail and are well- organized • Tables/figures clearly and concisely convey the data. • Statistical analyses (if used) are appropriate tests and are accurately interpreted. • Suggestions for further research in this area are insightful and thoughtful

	in this area are very limited.	adequate	
Presentaton (15)	<ul style="list-style-type: none"> • Noticeable grammatical mistakes • Average presentation 	<ul style="list-style-type: none"> • Minimal grammatical mistakes • Good Presentation 	<ul style="list-style-type: none"> • No grammatical mistakes • Flawless presentation