

**DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY,
UTTAR PRADESH, LUCKNOW**



Syllabus

For

M.Pharm. (Pharmaceutical Marketing Management)

(Effective from the Session: 2016-17)

Course Structure and Evaluation Scheme for M. Pharm. Courses (All Subjects/ Specialization) (Effective from Session 2016-17)

PHARMACEUTICAL MARKETING MANAGEMENT

Semester-I

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPA101	Modern Pharmaceutical Analytical Techniques	3	0	0	3	20	10	70	--	--	100
2	MPM101/ MPM204	Entrepreneurship Management/ International Pharmaceutical Marketing	3	0	0	3	20	10	70	--	--	100
3	MPM102	Principles & Practice of Management	3	0	0	3	20	10	70	--	--	100
4	MPM103/ MPM202	Drug Regulatory Affairs & Intellectual Property Rights/ Pharmaceutical. Sales & Advertising Management	3	0	0	3	20	10	70	--	--	100
5	RPM101	Research Process & Methodology	3	0	0	3	20	10	70	--	--	100
6	MPA105	Modern Pharmaceutical Analytical Techniques Practical	-	-	2	1	--	--	--	20	30	50
7	MPM104	Pharmaceutical Marketing Management Practical-I	-	-	3	2	--	--	--	20	30	50
Total						18						600

Semester-II

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPM201	Pharmaceutical Marketing Research	3	0	0	3	20	10	70	--	--	100
2	MPM202/ MPM103	Pharmaceutical. Sales & Advertising Management/ Drug Regulatory Affairs & Intellectual Property Rights	3	0	0	3	20	10	70	--	--	100
3	MPM203	Pharmaceutical Marketing Management	3	0	0	3	20	10	70	--	--	100
4	MPM204/ MPM101	Entrepreneurship Management/ International Pharmaceutical Marketing	3	0	0	3	20	10	70	--	--	100
5	MPM205	Medical Device Regulations	3	0	0	3	20	10	70	--	--	100
6	MPM206	Pharmaceutical Marketing Management Practical-II	-	-	2	1	--	--	--	20	30	50
7	MPM207	Seminar-I (Synopsis)	-	-	3	2	--	--	--	50	--	50
Total						18						600

Semester-III

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPM301	Seminar-II	0	0	6	3	--	--	--	100	--	100
2	MPM302	Dissertation (Research Project Audit)	0	0	30	15	--	--	--	200	300	500
Total						18						600

Semester-IV

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPM401	Dissertation (Final)	0	0	36	18	--	--	--	200	400	600
Total						18						600

M. Pharm. (Pharmaceutical Marketing Management)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101)

Unit-I

UV-Visible spectroscopy: Introduction, theory and laws associated with UV-visible spectroscopy, chromophores, auxochromes and their interaction with UV-Vis radiations, choice of solvents and solvent effect. Woodward-Fieser rule and applications of UV-visible spectroscopy.

IR Spectroscopy: Theory, modes of molecular vibrations, factors affecting vibrational frequencies and applications of IR spectroscopy. FT-IR. Interpretation of IR spectra of organic compounds.

Unit-II

Mass spectrometry: Different ionization methods (EI, CI, FAB, ESI, MALDI), analyzers of quadrupole and time of flight. Fragmentation patterns and its rules, relative abundance of ions, molecular ion peak, meta stable ions, isotopic peaks, Mc-Lafferty rearrangement, ring rule. Applications of mass spectrometry.

Flame emission spectroscopy and atomic absorption spectroscopy: Principle, interferences and applications of flame emission spectroscopy and atomic absorption spectroscopy.

Unit-III

NMR Spectroscopy: Principle, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, solvent requirement in NMR, NMR active compounds, free induction decay, relaxation process and NMR signals in various compounds. Applications of NMR spectroscopy.

Unit-IV

Chromatography: Principle, chromatographic parameters, factors affecting and applications of: Thin Layer chromatography, column chromatography, gas chromatography, affinity chromatography, ion exchange chromatography, size exclusion chromatography, high performance liquid chromatography, high performance thin layer chromatography.

Unit-V

Miscellaneous techniques:

Thermal methods of analysis: Introduction, principle, instrumentation and application of TGA, DTA and DSC.

Electron microscopy: Principle, instrumentation and applications of scanning electron microscopy (SEM), transmission electron microscopy (TEM).

Radioimmuno assay: ELISA.

SUGGESTED BOOKS:

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Skoog D.A., Holler F.J., Crouch S. R., Instrumental Analysis, Indian Edition, Brooks/Cole, Boston.
3. Willard H.H., Merrit L.L., Dean J.A., Settle P.A., Instrumental Methods of analysis, 7th Edition, CBS Publishers and Distributors New Delhi.
4. Kemp W., Organic Spectroscopy, Palgrave, New York.
5. Becket A.H. and Stenlake J.B., Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
6. Pavia D.L., Lampman G.M., and Kriz G.S., Introduction to Spectroscopy, Harcourt College Publishers, Philadelphia.
7. Kalsi P.S., Spectroscopy of Organic Compounds, New Age International Publishers, New Delhi.
8. Florey K., Analytical Profile of Drug Substance (All volume), Academic Press, Elsevier, Massachusetts.
9. Chatten L.G., A Text Book of Pharmaceutical Chemistry, Vol. I and II, Marcel Dekker, New

- York.
10. Silverstein R.M., Spectrometric Identification of Organic compounds, John Wiley & Sons, New Jersey.
 11. Obonson J.W.R., Undergraduate Instrumental Analysis, Marcel Dekker Inc, New York.
 12. Parikh V.H., Absorption Spectroscopy of Organic Molecules, Addison-Wesley Publishing Co., London.
 13. Stahl E., Thin Layer Chromatography: A Laboratory Handbook, Springer, Berlin.

ENTREPRENEURSHIP MANAGEMENT (MPM101/MPM204)

Unit-I

Conceptual frame work: Concept need and process in entrepreneurship development, role of enterprise in national and global economy, types of enterprise, merits and demerits, government policies and schemes for enterprise development, institutional support in enterprise development and management.

Unit-II

Entrepreneur: Entrepreneurial motivation, dynamics of motivation, entrepreneurial competency concepts. Developing entrepreneurial competencies- Requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

Unit-III

Launching and organizing an enterprise: Environment scanning- Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT analysis. Resource mobilization- Finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

Unit-IV

Growth strategies and networking: Performance appraisal and assessment, profitability and control measures, demands and challenges, need for diversification. Future Growth- Techniques of expansion and diversification, vision strategies, joint venture, co-ordination and feasibility study.

unit-V

Preparing project proposal to start on new enterprise: Project work- Feasibility report, planning, resource mobilizations and implementation.

SUGGESTED BOOKS:

1. Akhauri M.M.P., Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich R.D. and Brush C.G., The Women Entrepreneurs, D.C. Health and Co., Toronto.
3. Hisrich R.D. and Peters M.P., Entrepreneurship-Starting, Developing and Managing a New Enterprise, Richard D. Inwin, INC, USA.
4. Meredith G.G. et al. Practice of Entrepreneurship, ILO, Geneva.
5. Patel V.C., Women Entrepreneurship: Developing New Entrepreneurs, EDII, Ahmadabad.

PRINCIPLES & PRACTICE OF MANAGEMENT (MPM102)

Unit-I

Management: Concept, nature, importance. Management: Art and science. Management as a profession. Management vs. administration. Management skills, levels of management, characteristics of quality managers.

Evolution of management: Early contributions, Taylor and scientific management, Fayol's administrative management, social system approach, decision theory approach. Social responsibility of managers and ethics in managing.

Unit-II

Introduction to functions of management

Planning: Nature, scope, objectives and significance of planning, types of planning, process of planning, barriers to effective planning.

Decision making: Types, procedure, evaluation and selection of alternatives.

Organizing: Concept, organization theories, forms of organizational structure, span of control, delegation of authority, authority and responsibility, organizational design.

Unit-III

Staffing: Concept, system approach, manpower planning, job design, recruitment and selection, training and development, performance appraisal.

Directing: Concept, direction and supervision.

Motivation: Concept, motivation and performance, special motivational techniques: money, participation, rewards systems.

Unit-IV

Leadership: Concept and functions, process and models of leadership development. Contemporary views on leadership: Transformational-transactional, charismatic-visionary leadership.

Controlling: Concept, types of control

Unit-V

Human resource management: Human resource planning, recruitment and interviewing, human resource development through various instrument viz. Job description, job evaluation, job analysis, performance and potential appraisal methods.

SUGGESTED BOOKS:

1. Stoner, Freeman and Gilbert Jr, Management, Prentice Hall of India, Delhi.
2. Harold K. and Heinz W., Essentials of Management, Tata McGraw Hill, New York.
3. Robbins and Coulter, Management, 9th Edition, Prentice Hall of India, Delhi.
4. Robbins S.P. and Decenzo D.A., Fundamentals of Management: Essential Concepts and Applications, Pearson Education, New Jersey.
5. Heinz W. and Harold K., Management: A Global and Entrepreneurial Perspective, McGraw Hill, New York.

DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS (MPM103/MPM202)

Unit-I

Definition, need for patenting, types of patents, conditions to be satisfied by an invention to be patentable, introduction to patent search. Parts of patents and filling of patents. Essential elements of patent: Guidelines for preparation of laboratory note book, non-obviousness in patent.

Unit-II

Role of GATT, TRIPS and WIPO.

Unit-III

Brief introduction to Trademark protection and WHO patents. IPR's and its types. Major bodies regulating Indian pharmaceutical sector.

Unit-IV

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA.

Unit-V

Regulatory requirements for contract research organization. Regulations for biosimilars.

SUGGESTED BOOKS:

1. Berry F.R. and Nash R.A., Pharmaceutical Process Validation, Vol-57 of Drugs and Pharmaceuticals, Taylor and Francis, London.
2. Evans J.R., Anderson D.R., Sweeny D.J. and Williams T.A., Applied Production and Operations Management, West Publishing Company, Eagan.
3. Ahuja K.K., GMP for Pharmaceutical Material Management, CBS Publishers, New Delhi.
4. ISO-9000: Norms and Explanations.

RESEARCH PROCESS & METHODOLOGY (RPM101)

Unit-I

Fundamentals of research: Meaning, objective and importance of research methodology, types of research (basic, applied and patent oriented), defining research problem, research design including various methods, research process and steps involved. Literature survey and documentation.

Unit-II

Data collection, analysis and hypothesis testing: Classification of data, methods of data collection, sample size, sampling procedure and methods. Data processing and graphical representation of data. Statistical inference and hypothesis: Types of hypothesis (experimental and non-experimental), hypothesis testing (Parametric and non-parametric tests), generalization and interpretation of results. Use of statistical softwares/ packages in data analysis (SPSS, Graph Pad Prism).

Unit-III

Multivariate analysis: Introduction to multivariate analysis (Linear and non linear methods) and their validation methods (Statistical parameters).

Research ethics, plagiarism and impact of research: Research ethics, responsibility and accountability of the researchers, ethical consideration during animal experimentation including CPCSEA guidelines. Plagiarism and use of plagiarism detection softwares such as-VIPER. Impact of research on environment and society, commercialization of research, intellectual ownership.

Unit-IV

Technical writing and reporting of research: Types of research report: Dissertation and thesis, research paper, review article, short communication, conference presentation, meeting report etc. Structure and organization of research reports: Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references, footnotes, tables and illustrations. Impact factor, rating, indexing and citation of journals. Detailed study of 'Instruction to Authors' of any research journal, a thorough understanding of steps involved in submitting articles electronically to any research journal (Registration, new article submission, tracking process, submitting revised articles).

Unit-V

Funding agencies and research grants: Introduction to various research funding agencies such as-DST, DBT, AICTE, UGC, CSIR, ICMR, AAYUSH, and DRDO along with their function in India. Writing a research project and procurement of research grant. Project cost analysis.

SUGGESTED BOOKS:

1. Kothari C.R., Research Methodology Methods and Techniques, Wishwa Prakashan, New Delhi.
2. Lokesh K., Methodology of Educational research, Vikash Publishing House Pvt. Ltd., New Delhi.
3. Kumar R., Research Methodology, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
4. Rao G.N., Research Methodology and Qualitative Methods, B.S. Publications, Hyderabad.
5. Saunders M., Lewis P. and Thornhill A., Research Methods for Business Students, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
6. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and Clinical Applications, Marcel Dekker, New York.
7. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, An introduction to Research Methodology, RBSA Publishers, Jaipur.
8. Fisher R.A. Statistical Methods for Research Works, Oliver and Boyd, Edinburgh.
9. Chow S.S. and Liu J.P., Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, New York.
10. Buncher C.R., Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL (MPA105)

1. Determination of the wavelength of maximum absorbance (λ max) of given compounds by UV-Visible spectrophotometry.
2. Quantitative estimation of Pharmacopoeial compounds by UV-Visible spectrophotometry.
3. UV-Vis spectrophotometric assay of pharmaceutical formulations containing Pharmacopoeial compounds as active ingredients.
4. Simultaneous estimation of multi component containing formulations by UV-Visible spectrophotometry.
5. Quantitative estimation of caffeine in beverages using UV-Vis spectrophotometer.
6. Study and interpretation of the FT-IR/IR spectra of given compounds.
7. Separation of the organic compounds from given mixture by thin layer chromatography (TLC).
8. Isolation of the organic compounds from given mixture by two-dimensional thin layer chromatography (2D-TLC).
9. Separation and quantitative estimation of organic compounds in the given mixture by thin layer chromatography (Preparative TLC).
10. Column packing and separation of organic compounds with the help of column chromatography.
11. Simultaneous estimation of any marketed formulation using RP-HPLC method.
12. Stability studies of marketed formulation by RP-HPLC method as per ICH guidelines.
13. Estimation of Sodium/ Potassium by flame photometry.

PHARMACEUTICAL MARKETING MANAGEMENT PRACTICAL-I (MPM104)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Project/ case study on market segmentation.
2. Project/ case study on estimation of demand of drug/cosmetics.
3. Project related to product life cycle (PLC).
4. Project related to pricing of drugs and cosmetics.
5. Study of factors influencing sources of brands in pharma sector.
6. Case study of GAP analysis of pharma industries.
7. Project on customer relation management with reference to drugs and cosmetics.
8. Case study with respect to planning and decision making.
9. Case study on motivation of sales force.
10. Case study on recruitment and selection of medical sales process.
11. Project/ case study on training of sales force.
12. Case study on marketing information system.
13. Project on various techniques of sampling.
14. Design of package to increase the sales of drugs/cosmetics.
15. Role of advertisement in sales promotion of OTC drugs/ cosmetics.
16. Role of packaging in sales promotion of OTC drugs/ cosmetics.
17. Role of pricing in selection of brands of cosmetics by consumers.
18. Case study on pricing in global market with respect to drugs/ cosmetics.
19. Study on international channels of distribution for drugs.
20. Development of international marketing strategies for drugs/cosmetics.
21. Study of pattern of global advertisement.
22. Critical study of EXIM policy with respect to drug.
23. Feasibility study of project proposal with reference to pharma product.
24. Critical study of approval process of new medical devices.
25. Study of life cycle of medical devices in Indian market.

Second Semester

PHARMACEUTICAL MARKETING RESEARCH (MPM201)

Unit-I

Introduction: Definition of marketing research, objective of marketing research, application of marketing research, limitation of marketing research.

Marketing information system: Concept, need for marketing information system, process of marketing information system, components of marketing information system. Marketing research process.

Unit-II

Research design: Various method of research design, important experimental research designs. Primary and secondary data: methods of collecting primary data, advantages and disadvantages of primary data and secondary data, essentials characteristics for selecting secondary data.

Basic methods of collecting data: Questionnaire method/ observation method- Advantages and disadvantages, methods of observation, precautions in preparation of questionnaire and collection of data.

Unit-III

Measurement and scaling: Types of scales, difficulty of measurement, sources of error, criteria for a good scale, development of marketing measures.

Attitude scales: Concept of attitude, component of attitude, general procedure in attitude scaling, rating methods, limitations of attitude measurement.

Sampling: Definition, objective of sampling, steps in sample design, various techniques of sampling, advantages and disadvantages of different techniques of sampling, difference between probability and non-probability sampling, problem associated with sampling, determining sample size.

Unit-IV

Data collection and preparation: Field work, data processing, analysis and estimation, hypothesis testing, bivariate analysis: Chi square, correlation, rank correlation, regression analysis, analysis of variance.

Unit-V

Report preparation: Types and layout of research report, precautions in preparing the research report, bibliography and annexure in report, drawing conclusions, giving suggestions and recommendation to the concerned persons.

SUGGESTED BOOKS:

1. Byod & Others, Marketing Research, All India Traveler Book Seller, Delhi.
2. Nargundkar, Marketing Research, Tata McGraw Hill, New York.
3. Luck D.J. and Rubin R.S., Marketing Research, Prentice Hall of India, New Delhi.
4. Tull D.S. and Hawkins D.I, Marketing Research: Measurement & Method, Prentice Hall of India, New Delhi.
5. Beri G.C., Marketing Research, Tata McGraw Hill, New York.
6. Churchill G.A. and Iacobuce D., Marketing Research Methodological Foundation, Cengage Learning, Boston.
7. Zikmund W.G. and Babin Barry J., Essence of Marketing Research, Cengage Learning, Boston.
8. Green Paul E., Tull Donald S. and Gerald A., Research for Marketing Decisions, Prentice Hall of India, New Delhi.

PHARMACEUTICAL SALES AND ADVERTISING MANAGEMENT (MPM202/MPM103)

Unit-I

Introduction: Selling as a part of marketing, sales management process, role of sales manager, concept of personal selling, sales management and salesmanship, process of personal selling, qualities of a successful salesman.

Unit-II

Goals in sales management: Goal setting process in sales management, analyzing market demand and sales potential, techniques of sales forecasting, preparation of sales budget, formulating selling strategies, designing sales territories and sales quota.

Unit-III

Sales force management: Organizing the sales force, designing the structure and size of sales force, recruitment and selection of sales force, leading and motivating the sales force, training and compensating the sales force, evaluating sales force performance

Unit-IV

Advertisement Management: Purpose and function of advertising. Advertising planning and decision making: Planning framework, communication and persuasion process. Social, legal and regulatory factors in advertising.

Group influence and word of mouth advertising: Reference group influence on brand choice, factors influencing the degree of group influence

Unit-V

Role of media, selection of media for advertising, formulation of message, art of copywriting.

Branding and packaging strategies: Brand equity, image and personality, packaging decisions, perceptual mapping of customers, control aspects of advertising, advertising budget.

SUGGESTED BOOKS:

1. Batra, R. Myers J.G. and Aaker D.A., Advertising Management, PHI Publications, Delhi.
2. Still R.R., Cundiff E.W., Govoni N.P., Sales Management, Decision Strategies and Cases, Prentice Hall India, Delhi.
3. Sangade C.H., Frybenger V. and Rotzoll K., Advertising Practice and Theory, AITBS Publisher & Distributors, Delhi.
4. Wells W., Burnett J., Moriarty S., Advertising Practice & Principles, PHI Publications, Delhi.
5. Arens W.F., Contemporary Advertising McGraw Hill/Irwin, New York.
6. Mohan M., Advertising Management, Tata McGraw Hill, New York.
7. Khan M., Sales and Distribution Management, Excel Books, Noida.
8. Gupta S.L., Sales and Distribution Management, Excel Books, Noida.
9. Ingram T.N., La Forge R.W. and Avila R.A., Sales Management Analysis and Decision Making, Harcourt College Publishers, California.
10. Stanton W.J. and Spiro R., Management of Sale Force, McGraw Hill/Irwin, New York.

PHARMACEUTICAL MARKETING MANAGEMENT (MPM203)

Unit-I

Introduction, definition, importance and scope of marketing. Philosophies of marketing management. Elements of marketing-Needs, wants, demands, customer, consumer, markets and marketers. Marketing vs selling, consumer markets and industrial markets.

Concept of marketing management, marketing- Mix, functions of marketing management, marketing Organizations.

Unit-II

Market Segmentation, segmenting the market, benefits/purpose and limitations of market segmentations, market segmentation procedure. Introduction and procedure of market targeting. Product positioning- Introduction, objectives, usefulness, differentiating the product, product positioning strategy

Unit-III

Marketing- Mix decisions, new product planning and development process, product-mix, role of product manager, management of new product launch. Product life cycle- Stages and strategies for different stages of PLC, branding, brand creation, factors influencing the brand in product life cycle

Unit-IV

Pricing decisions, pricing methods, pricing influences & strategies. Drug Price Control Order (DPCO).

Promotion: Promotion-mix, advertising, sales promotion, personal selling, publicity and public relations. Use of internet marketing like e-marketing and e-detailing

Unit-V

Strategic marketing- GAP analysis, Porter's five force model, Ansoff's matrix, SWOT analysis, customer relation management.

SUGGESTED BOOKS:

1. Kotler P., Marketing Management, Analysis, Planning, Implementations and Control, 12th Edition, Pearson Education, New Jersey.
2. Stanton W.J., Fundamentals of Marketing, McGraw Hill, New York.
3. Kotler P. and Graw A., Principles of Marketing, Pearson Education, New Jersey.
4. Kotler P. Lane K.K., Abraham K. and Jha M., Marketing Management: A South Asian Perspective, 12th Edition, Pearson Education, New Jersey.
5. Ramaswamy V.S. and Namakumari S., Marketing Management: Planning, Implementation and Control, 3rd Edition, MacMillian, Lucknow.
5. Etzel M.J., Walker B.J. and Stanton W.J., Marketing Concept and Cases, Tata McGraw Hill, New York.
6. McCarthy and Perreault, Basic Marketing: A Global Marketing Approach, 15th Edition, Tata McGraw Hill, New York.
7. Kurtz D.L. and Boone L.E., Principles of Marketing, Thomson India Edition, New Delhi.

INTERNATIONAL PHARMACEUTICAL MARKETING (MPM204/MPM101)

Unit-I

Overview of world business and framework of international marketing: Definition of international marketing, international dimensions of marketing, domestic vs. international marketing, process of internationalization, benefits of international marketing.

World market environment: Political environment-Political systems, political risks, indicators of political risk, analysis and measures to minimize political risk.

Legal environment- Legal systems, legal form of organization, multiplicity of legal environment, bribery, branch vs. subsidiary, counterfeiting, gray market.

Cultural environment- Culture and its characteristics, influence of culture on-Consumption; thinking; communication process and cultural universals.

World Trade Organizations (WTO)- Structure and overview of agreements

Unit-II

Planning for international marketing: Foreign market entry strategies- Exporting, licensing, joint ventures, strategic alliances, acquisitions, franchising, assembly operations, management contracts, turnkey operations, free trade zones.

Product policy and planning- Product design and standardization, developing an international product line, foreign product diversification, international branding decisions, international packaging.

Unit-III

Pricing in global marketing: International pricing strategy- Role of pricing, price standardization, pricing decisions, price distortion, transfer pricing, methods of financing and means of payment.

Marketing channels and physical distribution: International channels of distribution- Channel members, channel management, retailing in international scenario, international physical distribution.

Unit-IV

Advertising and promotion: International promotion strategies- Promotion mix (Advertising, sale promotion, personal selling, public relation and publicity), promotion and communication.

International advertising- patterns of global advertising, global advertising regulations, advertising media, and advertising budget.

Unit-V

Export-import policy in India: Salient features, international commercial terms (Incoterms). Import-export documentation- Bill of exchange, marine insurance policy, invoices and other documents. Transport documents- Bill of lading, airway bill, letter of credit (Meaning and types of letter of credit). Financing exports (Pre-shipment credit, post-shipment finance) and financing imports. Export credit insurance- Standard and specific policies, guarantees.

SUGGESTED BOOKS:

1. Onkvisit S., Shaw J., International Marketing, Pearson Education, New Jersey.
2. Cherunilam F., International Trade and Export Management, Himalaya Publishing House, Mumbai.
3. Varshney R.L. and Bhattacharya B., International Marketing Management, Sultan Chand & Sons, New Delhi.
4. Czinkota M., International Marketing, Thompson South-Western, Mason.
5. Graham C., International Marketing, McGraw-Hill Education, New York.
6. Jain S., International Marketing, Thompson South-Western, Mason.

MEDICAL DEVICE REGULATIONS (MPM205)

Unit-I

Medical devices: Introduction, differentiating medical devices from IVDs and combination products, history of medical device regulation, product lifecycle of medical devices, classification of medical devices.

IMDRF/GHTF: Introduction, organizational structure, purpose and functions, regulatory guidelines, working groups, summary technical document (STED), global medical device nomenclature (GMDN).

Unit-II

Ethics: Clinical investigation of medical devices, clinical investigation plan for medical devices, good clinical practice for clinical investigation of medical devices (ISO 14155:2011)

Quality: Quality system regulations of medical devices: ISO 13485, quality risk management of medical devices: ISO 14971, validation and verification of medical device, adverse event reporting of medical device

Unit-III

USA: Introduction, classification, regulatory approval process for medical devices (510k) premarket notification, pre-market approval (PMA), investigational device exemption (IDE) and *in vitro* diagnostics, quality system requirements. Basics of *in vitro* diagnostics, classification and approval process.

Unit-IV

European Union: Introduction, classification, regulatory approval process for Medical Devices (Medical Device Directive, CE certification process. Basics of *in vitro* diagnostics, classification and approval process.

Unit-V

Medical device regulations in world health organization (WHO): Registration procedures, quality system requirements and regulatory requirements.

Asia: Clinical trial regulations specific for medical devices, registration procedures, quality system requirements and regulatory requirements for Japan, India and China

SUGGESTED BOOKS:

1. Pisano D.J. and Mantus D., FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, CRC Press, USA.
2. Kahan J.S., Medical Device Development: A Regulatory Overview, Parexel International Corporation, Massachusetts, USA.
3. Tobin J.J. and Walsh G., Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics and Medical Devices, Wiley Blackwell, New Jersey, USA.
4. Medina C., Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics, CRC Press, USA.
5. Country Specific Guidelines from official websites.

PHARMACEUTICAL MARKETING MANAGEMENT PRACTICAL-II (MPM206)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Project/ case study on market segmentation.
2. Project/ case study on estimation of demand of drug/cosmetics.
3. Project related to product life cycle (PLC).
4. Project related to pricing of drugs and cosmetics.
5. Study of factors influencing sources of brands in pharma sector.
6. Case study of GAP analysis of pharma industries.
7. Project on customer relation management with reference to drugs and cosmetics.
8. Case study with respect to planning and decision making.
9. Case study on motivation of sales force.
10. Case study on recruitment and selection of medical sales process.
11. Project/ case study on training of sales force.
12. Case study on marketing information system.
13. Project on various techniques of sampling.
14. Design of package to increase the sales of drugs/cosmetics.
15. Role of advertisement in sales promotion of OTC drugs/ cosmetics.
16. Role of packaging in sales promotion of OTC drugs/ cosmetics.
17. Role of pricing in selection of brands of cosmetics by consumers.
18. Case study on pricing in global market with respect to drugs/ cosmetics.
19. Study on international channels of distribution for drugs.
20. Development of international marketing strategies for drugs/cosmetics.
21. Study of pattern of global advertisement.
22. Critical study of EXIM policy with respect to drug.
23. Feasibility study of project proposal with reference to pharma product.
24. Critical study of approval process of new medical devices.
25. Study of life cycle of medical devices in Indian market.

SEMINAR-I (SYNOPSIS) (MPM207)