



ज्ञानगंगा घरोघरी

VISHAL JUNNAR SEVA MANDAL'S
**VISHAL INSTITUTE OF PHARMACEUTICAL
EDUCATION & RESEARCH**

Dr. S. L. Jadhav
Principal

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P.C.I. Inst. Code : PCI-2620 | D.T.E. Inst. Code : 6361 | University I.D. No. : CPHP012670

1.2.1

**Number of Programs in which CBCS/Elective
course system implemented**



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SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF
SCIENCE AND TECHNOLOGY



COURSE STRUCTURE AND SYLLABUS

FINAL YEAR BACHELOR OF PHARMACY (B. Pharm.) 2019PATTERN
(EFFECTIVE FROM ACADEMIC YEAR 2022 – 2023)




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Table – VIII: Course of study for semester VIII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3/45	1	4
BP802T	Social and Preventive Pharmacy	3/45	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6/90	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12/180	-	6
Total		24/360	4	22

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	27
II	29
III	24
IV	28
V	26
VI	30
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	211




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Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharma. Marketing Management–Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardizations of Herbals –Theory							
BP807ET	Computer Aided Drug Design –Theory							
BP808ET	Cell and Molecular Biology –Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology							
BP811ET	Advanced Instrumentation Techniques – Theory	-	-	-	-	150	4 Hrs	150
BP812ET	Dietary Suppliments and Nutraceuticals							
BP813PW	Project Work	-	-	-	-	150	4 Hrs	150
Total		40	60	4 Hrs	100	450	16 Hrs	550




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BP803ET	PHARMACEUTICAL MARKETING (Theory)	45 Hours
Scope: The pharmaceutical industry not only needs highly qualified researchers, chemists and, 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. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management. Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry. Course Content:		
UNIT-I Marketing: Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. Pharmaceutical market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients 'choice of physician and retail pharmacist. Analyzing the Market; Role of market research.		10 Hours
UNIT-II Product decision: Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labelling decisions, Product management in pharmaceutical industry.		10 Hours
UNIT-III Promotion: 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.		10 Hours




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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. Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.	08 Hours
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). Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	07 Hours
Recommended Books: (Latest Editions) 1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi 2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi. 3. Dhruv Grewal and Michael Levy: Marketing, Tata MC GrawHill 4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India 5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition) 6. Ramaswamy, U.S. & Nanakamari, S.: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi. 7. Shanker, Ravi: Service Marketing, Excel Books, New Delhi 8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.	



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BP805ET	PHARMACOVIGILANCE (Theory)	45 Hours
Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions. Objectives: - At completion of this paper it is expected that students will be able to (know, do, and appreciate): - Understand importance of drug safety monitoring. - Explain History, development, National and international scenario of pharmacovigilance & comprehend dictionaries, coding and terminologies used in pharmacovigilance - Understand detection and assessment of new adverse drug reactions, Adverse drug reaction reporting systems and communication in pharmacovigilance, Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning. CIOMS requirements for ADR reporting - Comprehend methods of safety data during pre-clinical, clinical and post approval phases of drugs' lifecycle. - Write case narratives of adverse events and their quality. Course Content:		
UNIT-I Introduction to Pharmacovigilance History and development of Pharmacovigilance, Importance of safety monitoring of Medicine, WHO international drug monitoring programme, Pharmacovigilance Program of India (PvPI) Introduction to adverse drug reactions Definitions and classification of ADRs, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions Basic terminologies used in pharmacovigilance Terminologies of adverse medication related events, Regulatory terminologies		10 Hours




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UNIT-II Drug and disease classification Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses, International Nonproprietary Names for drugs Drug dictionaries and coding in pharmacovigilance WHO adverse reaction terminologies, MedDRA and Standardized MedDRA queries, WHO drug dictionary, Eudravigilance medicinal product dictionary Information resources in pharmacovigilance Basic drug information resources, Specialized resources for ADRs Establishing pharmacovigilance programme Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (CROs), Establishing a national programme.	10 Hours
UNIT-III Vaccine safety surveillance Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization Pharmacovigilance methods Passive surveillance – Spontaneous reports and case series, Stimulated reporting, Active surveillance – Sentinel sites, drug event monitoring and registries, Comparative observational studies – Cross sectional study, case control study and cohort study, Targeted clinical investigations Communication in pharmacovigilance Effective communication in Pharmacovigilance, Communication in Drug Safety Crisis management, Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	10 Hours
UNIT-IV Safety data generation Pre-clinical phase, Clinical phase, Post approval phase (PMS) ICH Guidelines for Pharmacovigilance Organization and objectives of ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies	08 Hours



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UNIT-V Pharmacogenomics of adverse drug reaction Genetics related ADR with example focusing PK parameters. CIOMS CIOMS Working Groups, CIOMS Form CDSCO (India) and Pharmacovigilance D&C Act and Schedule Y Differences in Indian and global pharmacovigilance requirements	07 Hours
Recommended Books (Latest edition): 1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers. 2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers. 3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers. 4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers. 5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers. 6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers. 7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers. 8. A Textbook of Clinical Pharmacy Practice - Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata 9. National Formulary of India 10. Text Book of Medicine by Yashpal Munjal 11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna 12. http://www.who.int/dynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297 13. http://www.ich.org/ 14. http://www.cioms.ch/ 15. http://cdsco.nic.in/ 16. http://www.who.int/vaccine_safety/en/ 17. http://www.ipc.gov.in/PvPI/pv_home.html	




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