SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.11)
Syllabus with effect from the Academic Year 2024-2025

PROGRAMME STRUCTURE

Bachelor of Pharmacy (B. Pharm) Semester: VIII

To Pass	At least 40% Marks in the aggregate of University and Internal examination in each course.							
Course Type	**Course code**	**Name of the course**	**Credit**	**Contact Hours per Week**	**Exam Duration in Hrs**	**Component of Marks**		
						Internal	**End Semester**	**Total**
Core Course	UP08CBPH01	Social and Preventive Pharmacy – Theory	4	4	3	25/10	75/30	100/40
	UP08CBPH02	Quality Assurance – Theory	4	4	3	25/10	75/30	100/40
Generic Elective Course	UP08GBPH01	Pharmaceutical Marketing Management – Theory	4 + 4 = 8	4 + 4 = 8	3 + 3 = 6	25/10	75/30	100/40
	UP08GBPH02	Pharmaceutical Regulatory Science – Theory				25/10	75/30	100/40
	UP08GBPH03	Pharmacovigilance – Theory				25/10	75/30	100/40
	UP08GBPH04	Quality Control and Standardization of Herbals – Theory				25/10	75/30	100/40
	UP08GBPH05	Computer Aided Drug Design – Theory				25/10	75/30	100/40
	UP08GBPH06	Cell and Molecular Biology – Theory				25/10	75/30	100/40
	UP08GBPH07	Cosmetic Science – Theory				25/10	75/30	100/40
	UP08GBPH08	Experimental Pharmacology – Theory				25/10	75/30	100/40
	UP08GBPH09	Advanced Instrumentation Techniques – Theory				25/10	75/30	100/40
	UP08GBPH10	Dietary Supplements and Nutraceuticals				25/10	75/30	100/40
	UP08GBPH11	Pharmaceutical Product Development - Theory				25/10	75/30	100/40
Skill Enhancement Course	UP08SBPH01	Biostatistics and Research Methodology – Theory	4	4	3	25/10	75/30	100/40
	UP08SBPH02	Project Work	6	12	4	50/20	100/40	150/60
		Total:	**26**	**-**	**-**	**175/70**	**475/190**	**650/260**

Semester VIII

Schemes for internal assessments and end semester examinations

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
UP08CBPH01	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08CBPH02	Quality Assurance - Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH01	Pharmaceutical Marketing Management – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH02	Pharmaceutical Regulatory Science – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH03	Pharmacovigilance – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH04	Quality Control and Standardization of Herbals – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH05	Computer Aided Drug Design – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH06	Cell and Molecular Biology – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH07	Cosmetic Science – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH08	Experimental Pharmacology – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH09	Advanced Instrumentation Techniques – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH10	Dietary Supplements and Nutraceuticals	10	15	1 Hr	25	75	3 Hrs	100
UP08GBPH11	Pharmaceutical Product Development - Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08SBPH01	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
UP08SBPH02	Project Work					150		150
Total		**50**	**75**	**5 Hrs**	**125**	**375**	**15 Hrs**	**650**

Any Two Elective Courses (From UP08GBPH01 to UP08GBPH11) are opted.

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08CBPH01	Title of the Course	SOCIAL AND PREVENTIVE PHARMACY - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.
Objectives:	After the successful completion of this course, the student shall be able to: 1. Acquire high consciousness/realization of current issues related to health and Pharmaceutical problems within the country and worldwide. 2. Have a critical way of thinking based on current healthcare development. 3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Course Content:

Unit	Description	Hours
I	**Concept of health and disease:** Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. **Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. **Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health **Hygiene and health:** personal hygiene and health care; avoidable habits.	**10**
II	**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.	**10**
III	**National health programs, its objectives, functioning and outcome of the following:** HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme	**10**
IV	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program.	**08**

V	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school	**07**

Suggested References:	
Sr. No	**References**
1	Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2	Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3	Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4	Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications.
5	Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS
6	Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:	
Sr. No	**Journals**
1	Research in Social and Administrative Pharmacy, Elsevier, Ireland

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08CBPH02	Title of the Course	QUALITY ASSURANCE - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs
Objectives:	Upon completion of the course student shall be able to: • understand the cGMP aspects in a pharmaceutical industry. • appreciate the importance of documentation. • understand the scope of quality certifications applicable to pharmaceutical industries • understand the responsibilities of QA & QC departments.

Course Content:		
Unit	**Description**	**Hours**
I	**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP **Total Quality Management (TQM):** Definition, elements, philosophies **ICH Guidelines**: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines **Quality by design (QbD)**: Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation:** Principles and procedures	**10**
II	**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. **Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials	**10**
III	**Quality Control:** Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	**10**
IV	**Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.	**08**

	Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records	
V	**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management	**07**

Suggested References:	
Sr. No	**References**
1	Quality Assurance Guide by organization of Pharmaceutical Products of India
2	Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69
3	Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications
4	A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5	How to Practice GMP's – P P Sharma
6	ISO 9000 and Total Quality Management – Sadhank G Ghosh
7	The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8	Good laboratory Practices – Marcel Deckker Series
9	ICH guidelines, ISO 9000 and 14000 guidelines

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH01	Title of the Course	PHARMACEUTICAL MARKETING MANAGEMENT - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

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.
Objectives:	The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Course Content:

Unit	Description	Hours
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**
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 labeling decisions, Product management in pharmaceutical industry.	**10**
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**
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	**8**

	customer calls, motivating, evaluating, compensation and future prospects of the PSR.	
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.	**7**

Suggested References:	
Sr. No	**References**
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 Graw Hill.
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 Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7	Shanker, Ravi: Service Marketing, Excell Books, New Delhi.
8	Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH02	Title of the Course	PHARMACEUTICAL REGULATORY SCIENCE - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.
Objectives:	Upon completion of the subject student shall be able to: 1. Know about the process of drug discovery and development. 2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals. 3. Know the regulatory approval process and their registration in Indian and international markets.

Course Content:

Unit	Description	Hours
I	**New Drug Discovery and development** Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development	**10**
II	**Regulatory Approval Process** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. **Regulatory authorities and agencies** Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)	**10**
III	**Registration of Indian drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.	**10**
IV	**Clinical trials** Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.	**8**

V	**Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.	**7**

Suggested References:	
Sr. No	**References**
1	Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan
2	The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers
3	New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190
4	Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc
5	FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6	Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7	Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams.
8	Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9	Drugs: From Discovery to Approval, Second Edition By Rick Ng

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH03	Title of the Course	PHARMACOVIGILANCE - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

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):* 1. Why drug safety monitoring is important? 2. History and development of pharmacovigilance. 3. National and international scenario of pharmacovigilance. 4. Dictionaries, coding and terminologies used in pharmacovigilance. 5. Detection of new adverse drug reactions and their assessment. 6. International standards for classification of diseases and drugs. 7. Adverse drug reaction reporting systems and communication in pharmacovigilance. 8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle. 9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation. 10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India. 11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning. 12. CIOMS requirements for ADR reporting. 13. Writing case narratives of adverse events and their quality.

Course Content:		
Unit	**Description**	**Hours**
I	**Introduction to Pharmacovigilance** • History and development of Pharmacovigilance • Importance of safety monitoring of Medicine • WHO international drug monitoring program • 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**	**10**

	• Terminologies of adverse medication related events • Regulatory terminologies	
II	**Drug and disease classification** • Anatomical, therapeutic and chemical classification of drugs • International classification of diseases • Daily defined doses • International Non proprietary Names for drugs **Drug dictionaries and coding in pharmacovigilance** • WHO adverse reaction terminologies • MedDRA and Standardised MedDRA queries • WHO drug dictionary • Eudravigilance medicinal product dictionary **Information resources in pharmacovigilance** • Basic drug information resources • Specialised resources for ADRs **Establishing pharmacovigilance programme** • Establishing in a hospital • Establishment & operation of drug safety department in industry • Contract Research Organisations (CROs) • Establishing a national programme	**10**
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**
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	**08**

	• Good clinical practice in pharmacovigilance studies	
V	**Pharmacogenomics of adverse drug reactions** • Genetics related ADR with example focusing PK parameters. **Drug safety evaluation in special population** • Paediatrics • Pregnancy and lactation • Geriatrics **CIOMS** • CIOMS Working Groups • CIOMS Form **CDSCO (India) and Pharmacovigilance** • D&C Act and Schedule Y • Differences in Indian and global pharmacovigilance requirements	**07**

Suggested References:	
Sr. No	**References**
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 Pharmacoepidemiolog 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 NyfortHansen,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.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=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

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH04	Title of the Course	QUALITY CONTROL AND STANDARDIZATION OF HERBALS - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.
Objectives:	Upon completion of the subject student shall be able to; 1. know WHO guidelines for quality control of herbal drugs 2. know Quality assurance in herbal drug industry 3. know the regulatory approval process and their registration in Indian and international markets 4. appreciate EU and ICH guidelines for quality control of herbal drugs

Course Content:		
Unit	**Description**	**Hours**
I	Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms. WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use	**10**
II	**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines. WHO Guidelines on GACP for Medicinal Plants	**10**
III	EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	**10**
IV	Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions	**08**
V	Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products	**07**

Suggested References:	
Sr. No	**References**
1	Pharmacognosy by Trease and Evans
2	Pharmacognosy by Kokate, Purohit and Gokhale
3	Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006
4	Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002
5	EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6	Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002
7	Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8
8	WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998
9	WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981
10	WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999
11	WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005
12	WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH05	Title of the Course	COMPUTER AIDED DRUG DESIGN - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process
Objectives:	Upon completion of the course, the student shall be able to understand; • Design and discovery of lead molecules • The role of drug design in drug discovery process • The concept of QSAR and docking • Various strategies to develop new drug like molecules. • The design of new drug molecules using molecular modeling software

Course Content:

Unit	Description	Hours
I	**Introduction to Drug Discovery and Development** Stages of drug discovery and development **Lead discovery and Analog Based Drug Design** Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation. **Analog Based Drug Design:** Bioisosterism, Classification, Bioisosteric replacement. Any three case studies	**10**
II	**Quantitative Structure Activity Relationship (QSAR)** SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA	**10**
III	**Molecular Modeling and virtual screening techniques Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, **Molecular docking**: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design	**10**
IV	**Informatics & Methods in drug design** Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases	**08**
V	**Molecular Modeling:** Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination	**07**

Suggested References:	
Sr. No	**References**
1	Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore
2	Martin YC. "Quantitative Drug Design" Dekker, New York
3	Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York
4	Foye WO "Principles of Medicinal chemistry 'Lea & Febiger
5	Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience
6	Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York
7	Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press
8	Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston
9	Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH06	Title of the Course	CELL AND MOLECULAR BIOLOGY - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	• Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. • This is done both on a microscopic and molecular level. • Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges
Objectives:	Upon completion of the subject student shall be able to; • Summarize cell and molecular biology history. • Summarize cellular functioning and composition. • Describe the chemical foundations of cell biology. • Summarize the DNA properties of cell biology. • Describe protein structure and function. • Describe cellular membrane structure and function. • Describe basic molecular genetic mechanisms. • Summarize the Cell Cycle.

Course Content:

Unit	Description	Hours
I	a) Cell and Molecular Biology: Definitions theory and basics and Applications. b) Cell and Molecular Biology: History and Summation. c) Properties of cells and cell membrane. d) Prokaryotic versus Eukaryotic e) Cellular Reproduction f) Chemical Foundations – an Introduction and Reactions (Types)	**10**
II	a) DNA and the Flow of Molecular Information b) DNA Functioning c) DNA and RNA d) Types of RNA e) Transcription and Translation	**10**
III	a) Proteins: Defined **and** Amino Acids b) Protein Structure	**10**

	c) Regularities in Protein Pathways d) Cellular Processes e) Positive Control and significance of Protein Synthesis	
IV	a) Science of Genetics b) Transgenics and Genomic Analysis c) Cell Cycle analysis d) Mitosis and Meiosis e) Cellular Activities and Checkpoints	**08**
V	a) Cell Signals: Introduction b) Receptors for Cell Signals c) Signaling Pathways: Overview d) Misregulation of Signaling Pathways e) Protein-Kinases: Functioning	**07**

Suggested References:

Sr. No	References
1	W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London
2	Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi
3	Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn
4	Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology
5	Rose: Industrial Microbiology
6	Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7	Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution
8	Peppler: Microbial Technology
9	Edward: Fundamentals of Microbiology
10	N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11	Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12	B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13	RA Goldshy et. al., : Kuby Immunology

Bachelor of Pharmacy
B. Pharm Semester VIII

Course Code	UP08GBPH07	Title of the Course	COSMETIC SCIENCE - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject covers foundational topic that are important for understanding the principles of various excipients and technologies used in manufacturing various kinds of cosmetic products.
Objectives:	This module aims to provide an understanding of the concepts behind the drug manufacturing in pharmaceutical industry. By the end of the course, students should be able to: 1. Understand the comprehensive knowledge about working of various excipients used in cosmetic products. 2. Understand various principles and technologies to manufacture skin care and other cosmetic products. 3. To understand the use and techniques for manufacturing of various herbal formulations.

Course Content:		
Unit	**Description**	**Hours**
I	Classification of cosmetic and cosmeceutical products Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs. **Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application. **Skin:** Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle. **Oral Cavity:** Common problem associated with teeth and gums	**10**
II	**Principles of formulation and building blocks of skin care products:** Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmecuticals. **Antiperspants & deodorants**- Actives & mechanism of action. **Principles of formulation and building blocks of Hair care products:** Conditioning shampoo, Hair conditioner,anti-dandruff shampoo. Hair oils. Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.	**10**
III	Sun protection, Classification of Sunscreens and SPF. **Role of herbs in cosmetics:** Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove	**10**

	Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.	
IV	Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps,and syndet bars. Evolution and skin benfits.	**08**
V	Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants- Actives and mechanism of action.	**07**

Suggested References:	
Sr. No	**References**
1	Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2	Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3	Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

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B. Pharm Semester VIII

Course Code	UP08GBPH08	Title of the Course	EXPERIMENTAL PHARMACOLOGY - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results
Objectives:	Upon completion of the course the student shall be able to, • Appreciate the applications of various commonly used laboratory animals. • Appreciate and demonstrate the various screening methods used in preclinical Research • Appreciate and demonstrate the importance of biostatistics and research methodology • Design and execute a research hypothesis independently.

Course Content:

Unit	Description	Hours
I	**Laboratory Animals:** Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	**10**
II	**Preclinical screening models** **a)** Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. **b) Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's, antiasthmatics, **c) Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	**10**
III	**Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	**10**
IV	**Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti-aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	**10**
V	**Research methodology and Bio-statistics** Selection of research topic, review of literature, research hypothesis and study design	**05**

	Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data.	

Suggested References:	
Sr. No	**References**
1	Fundamentals of experimental Pharmacology-byM.N.Ghosh
2	Hand book of Experimental Pharmacology-S.K.Kulakarni
3	CPCSEA guidelines for laboratory animal facility
4	Drug discovery and Evaluation by Vogel H.G.
5	Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6	Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard.

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B. Pharm Semester VIII

Course Code	UP08GBPH09	Title of the Course	ADVANCED INSTRUMENTATION TECHNIQUES - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.
Objectives:	Upon completion of the course the student shall be able to • understand the advanced instruments used and its applications in drug analysis • understand the chromatographic separation and analysis of drugs. • understand the calibration of various analytical instruments • know analysis of drugs using various analytical instruments.

Course Content:

Unit	Description	Hours
I	**Nuclear Magnetic Resonance spectroscopy** Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications	**10**
II	**Thermal Methods of Analysis**: Principles, instrumentation and applications of Thermo gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) **X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, X- ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.	**10**
III	**Calibration and validation-**as per ICH and USFDA guidelines Calibration of following Instruments Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC	**10**
IV	**Radio immune assay:**Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay **Extraction techniques**:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.	**08**
V	**Hyphenated techniques**-LC-MS/MS, GC-MS/MS, HPTLC-MS.	**07**

Suggested References:	
Sr. No	**References**
1	Instrumental Methods of Chemical Analysis by B.K Sharma
2	Organic spectroscopy by Y.R Sharma
3	Text book of Pharmaceutical Analysis by Kenneth A. Connors
4	Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5	Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6	Organic Chemistry by I. L. Finar
7	Organic spectroscopy byWilliam Kemp
8	Quantitative Analysis of Drugs by D. C. Garrett
9	Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10	Spectrophotometric identification of Organic Compounds by Silverstein

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Course Code	UP08GBPH10	Title of the Course	DIETARY SUPPLEMENTS AND NUTRACEUTICALS - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.
Objectives:	This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to: 1. Understand the need of supplements by the different group of people to maintain healthy life. 2. Understand the outcome of deficiencies in dietary supplements. 3. Appreciate the components in dietary supplements and the application. 4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

Course Content:

Unit	Description	Hours
I	a) Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. b) Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. c) Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds. d) Functional foods for chronic disease prevention.	**10**
II	Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin. b) Sulfides: Diallyl sulfides, Allyl trisulfide. c) Polyphenolics: Reservetrol. d) Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans g) Tocopherols h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.	**10**
III	a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins,	**7**

	Carbohydrates, nucleic acids. b) Dietary fibres and complex carbohydrates as functional food ingredients.	
IV	a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing. b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.	**08**
V	a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.	**10**

Suggested References:	
Sr. No	**References**
1	Dietetics by Sri Lakshmi
2	Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication
3	Advanced Nutritional Therapies by Cooper. K.A., (1996)
4	The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988)
5	Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6	G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London
7	Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York
8	Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press
9	Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10	Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

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B. Pharm Semester VIII

Course Code	UP08GBPH11	Title of the Course	PHARMACEUTICAL PRODUCT DEVELOPMENT - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	This subject covers foundational topic that are important for understanding the need and requirements of various excipients used in pharmaceutical industry and the way of manufacturing robust product as per latest guidelines.
Objectives:	This module aims to provide an understanding of the concepts behind the drug manufacturing in pharmaceutical industry. By the end of the course, students should be able to: 1. Understand the use and properties of various pharmaceutical excipients suitable for a particular dosage form. 2. Understand the concepts of QbD followed in pharmaceutical industry for manufacturing robust product and precise processing parameters. 3. Understand various regulatory requirements for the packaging material suitable to different pharmaceutical products.

Course Content:		
Unit	**Description**	**Hours**
I	Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms.	**10**
II	An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories. I. Solvents and solubilizers. II. Cyclodextrins and their applications. III. Non - ionic surfactants and their applications IV. Polyethylene glycols and sorbitols V. Suspending and emulsifying agents VI. Semi solid excipients	**10**
III	An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories I. Tablet and capsule excipients II. Directly compressible vehicles III. Coat materials IV. Excipients in parenteral and aerosols products V. Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications.	**10**

IV	Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples.Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.	**08**
V	Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations	**07**

Suggested References:

Sr. No	**References**
1	Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc
2	Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition,Informa Healthcare publishers
3	Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc
4	The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013
5	Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd
6	Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012
7	Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8	Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed
9	Remington – The Science and Practice of Pharmacy, 20th Ed
10	Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
11	Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker
12	Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann
13	Advanced Review Articles related to the topics

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Course Code	UP08SBPH01	Title of the Course	BIOSTATISITCS AND RESEARCH METHODOLOGY - Theory
Total Credits of the Course	4	Hours per Week	3 + 1 (Tutorial)

Scope	To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel
Objectives:	Upon completion of this course the student should be able to 1. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment). 2. Know the various statistical techniques to solve statistical problems. 3. Appreciate statistical techniques in solving the problems.

Course Content:

Unit	Description	Hours
I	**Introduction:** Statistics, Biostatistics, Frequency distribution **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples. **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems. **Correlation**: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples	**10**
II	**Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples. **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples **Parametric test**: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference	**10**
III	**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.	**10**

	Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.	
IV	Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression models **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach.	**08**
V	**Design and Analysis of experiments:** **Factorial Design:** Definition, 2^2, 2^3design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques.	**07**

Suggested References:	
Sr. No	**References**
1	Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork
2	Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3	Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam
4	Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

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B. Pharm Semester VIII

Course Code	UP08SBPH02	Title of the Course	PROJECT WORK
Total Credits of the Course	6	Hours per Week	12

Course Content:

Description

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII or any minor research project. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

A coordinator faculty member will be appointed for the project work. Project work coordinator facilitates the Guide/Mentor Allocation, time-table announcement, assessment schedule and submission requirements.

A project work shall be a minor project. A project work may be based upon Laboratory study, Survey oriented, Computational study, Review based, Extension of practice school, Business Plan for Startup. A project may be undertaken at pharmaceutical industry, research and development centre, CRO, public testing laboratory, hospital, community pharmacy and at institute where B. Pharm Program is pursuing.

Submission:

Student(s) shall submit the proposal of project work (Title, Rationale, Objectives, Methodology and Work Plan) at the starting of Sem VIII. The program committee will evaluate and approve the proposal.

Student(s) shall submit followings before the scheduled date of end semester examination to project work coordinator, forwarded through the guide.

1. Record Book – Student should record day to day observations, information gathered, findings and suggestions from guide in a hard bound record book. It should also contain the graphs, figures, data tables.
2. Progress Report (at the end of 50 Hrs and 100 Hrs) along with attendance record
3. Dissertation Report (as per the prescribed format)
4. Presentation handouts

Evaluation:

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below

Evaluation of Dissertation Report:

Objective(s) of the work done		15 marks
Methodology adopted		20 marks
Results and discussion		20 marks
Conclusions and outcomes		20 marks
	Total	**75 marks**

Evaluation of Presentation:

Presentation of work		25 marks
Communication skills		20 marks
Questions and Answer		30 marks
	Total	**75 marks**