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)

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS)of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester:

Each semestershall consist of not less than 90 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the

other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

7.2. Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree **is 211**. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Projectover the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus. The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

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 Suppliments 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**

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							
BP812ET	Dietary Suppliments and Nutraceuticals							
BP813PW	Project Work	-	-	-	-	150	4 Hrs	150
Total		**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

SEMESTER – VIII

BP801T	BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)	45 Hours

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 the course the student shall 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-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,KarlPearson'scoefficientofcorrelation,Multiplecorrelation-Pharmaceuticals examples	**10 Hours**
UNIT-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,largesample,smallsample,Null hypothesis,alternativehypothesis,sampling,essenceofsampling,typesofsampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples **Parametric test**: t-test(Sample, Pooled or Unpaired and Paired),ANOVA,(Oneway and Two way),Least Significance difference	**10 Hours**

UNIT-III **Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test **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 ofdata, Protocol,Cohortsstudies, Observational studies,Experimental studies,Designingclinical trial, various phases.	**10 Hours**
UNIT-IV Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression nmodels **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 Hours**
UNIT-V **Design and Analysis of experiments:** **Factorial Design:** Definition, 2^2, 2^3 design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques	**07 Hours**
Recommended Books (Latest edition): 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 andC.Montgomery	

BP802T	SOCIAL AND PREVENTIVE PHARMACY (Theory)	45 Hours

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 andworldwide.
2. Develop a critical way of thinking based on current health care development.
3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Course Content:

UNIT-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. **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 Hours**
UNIT-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 Hours**
UNIT-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 Hours**
UNIT-IV National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria PreventionProgram, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program	**08 Hours**

UNIT-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 Hours**
Recommended Books (Latest edition): 1. ShortTextbookofPreventiveandSocialMedicine,PrabhakaraGN,2nd Edition,2010, ISBN: 9789380704104, JAYPEE Publications 2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy RabindraNath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications 3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6thEdition, 2014, ISBN: 9789351522331, JAYPEEPublications 4. Essentials of Community Medicine: A Practical Approach, Hiremath Lalita D, HiremathDhananjaya 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 BHANOTPUBLISHERS. 6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers,Hyderabad **Recommended Journals:** 1. Research in Social and Administrative Pharmacy, Elsevier, Ireland	

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**

UNIT-IV **Pharmaceutical marketing channels:** Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks inphysical distributionmanagement. **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 ofIndia, NewDelhi 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. RajanSaxena: Marketing Management; Tata MC Graw-Hill (IndiaEdition) 6. Ramaswamy,U.S&Nanakamari,S:MarketingManagemnt:GlobalPerspective,Indian Context, Macmilan India, NewDelhi. 7. Shanker, Ravi: Service Marketing, Excell Books, NewDelhi 8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series)Excel Publications.	

BP804ET	PHARMACEUTICAL REGULATORY SCIENCE (Theory)	45 Hours

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 andsale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian andinternational markets.

Course content:

UNIT-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 Hours**
UNIT-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 Hours**
UNIT-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 Hours**

UNIT-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	**08 Hours**
UNIT-V **Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	**07 Hours**
Recommended books (Latest edition): • Drug Regulatory Affairs by SachinItkar, Dr. N.S. Vyawahare, NiraliPrakashan. • The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. InformaHealth carepublishers. • New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino,MD,5th edition, Drugsand the Pharmaceutical Sciences, Vol.190. • Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley &Sons. Inc. • FDA Regulatory Affairs: a guide for prescription drugs, medical devices, andbiologics • /edited by Douglas J. Pisano, David Mantus. • Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland IsaderKaufer, Marcel Dekker series,Vol.143 • Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance By Fay A. Rozovsky and Rodney K.Adams • Principles and Practices of Clinical Research, Second Edition Edited by JohnI. Gallin and Frederick P.Ognibene • Drugs: From Discovery to Approval, Second Edition By RickNg	

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 andsignaldetection.Thispaperalsodevelopstheskillsofclassifyingdrugs,diseasesand adverse drugreactions

Objectives:

- At completion of this paper it is expected that students will be able to (know, do, and appreciate):
- Understand importance of drug safetymonitoring.
- 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 ADRreporting
- Comprehend methods of safety data during pre-clinical, clinical andpost 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**

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**

UNIT-V **Pharmacogenomics of adverse drug reaction** Genetics related ADR with example focusing PK parameters. **CIOMS** CIOMSWorking Groups, CIOMS Form **CDSCO (India) and Pharmaco - vigilance** 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, MedicalPublishers.
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, WileyPublishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, PatrickWalle, WileyPublishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& BartlettPublishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, WileyPublishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen, Milap C.Nahata
9. National Formulary ofIndia
10. Text Book of Medicine by YashpalMunjal
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&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

BP806ET	QUALITY CONTROL AND STANDARDIZATION OF HERBALS(Theory)	45 Hours

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-I Basic tests for drugs – Pharmaceutical substances, Medicinal plants materialsand dosage forms, WHO guidelines for quality control of herbal drugs, Evaluation of commercial crude drugs intended foruse	**10 Hours**
UNIT-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 Hours**
UNIT-III • EU and ICH guidelines for quality control of herbal drugs. • Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	**10 Hours**
UNIT-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 Hours**

UNIT-V Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Comparison of various Herbal Pharmacopoeias. **Recommended Books (Latest Editions)** • Role Pharmacognosy by Trease and Evans • Pharmacognosy by Kokate, Purohit andGokhale • Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I,Carrier Pub., 2006. • Aggrawal, S.S., Herbal Drug Technology. Universities Press,2002. • EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products, • Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India,2002. • 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. • 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. • WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rdedn. World Health Organization, Geneva,1981. • WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva,1999. • 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. • WHO. Guidelines on Good Agricultural and Collection Practices (GACP)for Medicinal Plants. World Health Organization, Geneva, 2004.	**07 Hours**

BP807ET	COMPUTER AIDED DRUG DESIGN (Theory)	45 Hours

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

1. Understand the design and discovery of leadmolecules
2. Classify the role of drug design tools for drug discoveryprocess
3. Understand and analyse concepts of QSAR anddocking
4. Analyse and apply various strategies to develop new drug likemolecules.
5. Use various molecular modeling software to design new drugmolecule

Course Content

UNIT-I **Introduction to Drug Discovery and Development -** Stages of drug discovery and development, Lead discovery approaches - 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. **Introduction to Ligand based and Structure Based DD** **Analog Based Drug Design -** Bioisosterism, Bioisosteric replacement **Case studies -** Ligand based (Design of inhibitors of tubulin polymerization eg. Colchicine), Structure based (Design of HMG-CoA reductase inhibitors. eg. Statins) and Analog based DD (Design of H2 histamine antagonist eg. Cimetidine)	**14 Hours**
UNIT- II **Introduction to Computational tools Molecular Modeling -** Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination. **Molecular docking -** Rigid docking, flexible docking, manual docking, Docking based screening.	**10 Hours**
UNIT- III **Quantitative Structure Activity Relationship (QSAR) and Pharmacophore modeling** **Introduction -** SAR versus QSAR, History and development of QSAR, Types of physicochemicalparameters **2D QSAR -** Experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch's analysis, Free Wilson analysis **3D-QSAR approaches -** COMFA and COMSIA. **Pharmacophore modeling -** Drug likeness screening, Concept of Pharmacophore mapping and Pharmacophore based screening	**14 Hours**

UNIT- IV **Informatics & Methods in drug design** Introduction to Bioinformatics, chemo informatics **Databases -** Chemical database, Natural compound database, Drug like compound database , Drug bank	**07 Hours**
Recommended Books (Latest Editions) 1. Robert GCK, ed., "Drug Action at the Molecular Level" University PrakPress Baltimore. 2. Martin YC. "Quantitative Drug Design" Dekker,NewYork. 3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of OrganicMedicinal & Pharmaceutical Chemistry" Lippincott,NewYork. 4. Foye WO "Principles of Medicinal chemistry 'Lea&Febiger. 5. Korolkovas A, BurckhalterJH. "Essentials of Medicinal Chemistry" Wiley Interscience. 6. WolfME,ed"TheBasisofMedicinalChemistry,Burger'sMedicinalChemistry" John Wiley & Sons,NewYork. 7. PatrickGraham,L.,AnIntroductiontoMedicinalChemistry,OxfordUniversityPress. 8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" WrightBoston. 9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action"Academic Press NewYork. 10. D. J. Triggle, John Bodenhan Taylor, Peter Kennewell, Comprehensive Medicinal Chemistry, Volume I-VIII : Germany: Elsevier Science.	

BP808ET	CELL AND MOLECULAR BIOLOGY (Theory)	45 Hours

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 lifecycle, 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:

1. Summarize cell and molecular biology history, cellular functioning and Composition & describe the chemical foundations of cell biology.
2. Describe cellular membrane structure and function properties and functionsof DNA, CellCycle.
3. Describe basic molecular genetics mechanisms.
4. Understand the cell signaling pathways with their regulations and role indisease process.

Course contents

UNIT-I Cell and Molecular Biology: Definitions theory and basics and Applications. Cell and Molecular Biology: History and Summation. Properties of cells and cell membrane, Prokaryotic versus Eukaryotic, Cellular Reproduction, Chemical Foundations – an Introduction and Reactions (Types)	**10 Hours**
UNIT-II DNA and the Flow of Molecular Information, DNA Functioning, DNA and RNA, Types of RNA, Transcription and Translation	**10 Hours**
UNIT-III Proteins: Defined and Amino Acids, Protein Structure, Regularities in Protein Pathways, Cellular Processes, Positive Control and significance of Protein Synthesis	**10 Hours**
UNIT-IV Science of Genetics, Transgenics and Genomic Analysis, Cell Cycle analysis, Mitosis and Meiosis, Cellular Activities and Checkpoints Clinical phase, Post approval phase (PMS)	**08 Hours**

UNIT-V Cell Signals: Introduction, Receptors for Cell Signals, Signaling Pathways: Overview, Misregulation of Signaling Pathways, Protein-Kinases: Functioning	**07 Hours**
Recommended Books (latest edition): 1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology,Blackwell Scientific publications, OxfordLondon. 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: PharmaceuticalMicrobiology. Rose: IndustrialMicrobiology. 5. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed.Japan 6. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution. Peppler: MicrobialTechnology. 7. Edward: Fundamentals ofMicrobiology. 8. N.K.Jain: Pharmaceutical Microbiology, VallabhPrakashan,Delhi 9. Bergeys manual of systematic bacteriology, Williams and Wilkins- A WaverlyCompany 10. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principlesand 11. Applications of Recombinant DNA: ASM Press Washington D.C. RA Goldshyet. al., :KubyImmunology.	

BP809ET	COSMETIC SCIENCE (Theory)	45 Hours
Scope: Thiscourseisdesignedtoimpartfundamentalknowledgeofcosmeticandcosmeceutical products &their formulationstudies. **Objectives:** Upon completion of the course, the student shall be able to: 1. Understand the concepts of cosmetics; anatomy of skin v/s hair, general excipients used incosmetics. 2. Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals & cosmeceuticals agents 3. Know different Laws and Acts that regulate pharmaceutical industry 4. Understand the approval process and regulatory requirements for drug products **Course contents**		
UNIT-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 Hours**
UNIT-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 cosmeceuticals. **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 hairdye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.		**10 Hours**

UNIT-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 **Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin cream and toothpaste**.**	**10 Hours**
UNIT-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 Hours**
UNIT-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 Hours**
References 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, GeorgeGodwin. 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, TataPublishers.	

BP810ET	EXPERIMENTAL PHARMACOLOGY (Theory)	45 Hours

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,

1. Understand the applications of various commonly used laboratory animals.
2. Demonstrate the various screening methods used in preclinical research.
3. Comprehend and demonstrate the importance of biostatistics and research methodology.
4. Design and execute a research hypothesis independently.

Course contents

UNIT-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 Hours**
UNIT-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 positivecontrolgroups.Rationaleforselectionofanimalspeciesandsexforthestudy. b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease.	**10 Hours**
UNIT-III **Preclinical screening models:** ForANSactivity,sympathomimetics,sympatholytics,parasympathomimetics,parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	**10 Hours**

UNIT-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	**08 Hours**
UNIT-V Research methodology and Bio-statistics. Selection of research topic, review of literature, research hypothesis and study design Pre- clinical data analysis and interpretation using Students‘t’ test and One-way ANOVA. Graphical representation ofdata	**07 Hours**
Recommended Books (latest edition): 1. Fundamentals of experimental Pharmacology-byM. N.Ghosh 2. Hand book of Experimental Pharmacology-S.K. Kulkarni 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	

BP811ET	ADVANCED INSTRUMENTATION TECHNIQUES (Theory)	45 Hours

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 drugtesting.

Objectives:

Upon completion of the course the student shall be able to

1. Express the principle of the advanced instruments used and justify its applications in drug analysis
2. Understand the principles of analytical techniques and its application in analysis of drugs
3. Explain the importance and methods for the calibration of various analytical instruments
4. Formulate and justify techniques for the analysis of drugs using various analytical instruments.

Course contents

UNIT-I **Nuclear Magnetic Resonance spectroscopy** Principles of ^{1}H-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications **^{13}C-NMR-** Introduction to ^{13}C-NMR spectroscopy **Mass Spectrometry** Principles, , Ionization techniques –Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, Fragmentation, applications **Simple structural elucidation problems**	**14 Hours**
UNIT-II **Thermal Methods of Analysis** Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)	**07 Hours**
UNIT-III **Electrophoresis** Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel,capillary electrophoresis, applications **X-Ray Diffraction Methods**	**10 Hours**

Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, and applications. **Calibration of following Instruments** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, HPLC.	
UNIT-IV **Radio immuno assay** Principle, different methods, Importance, various components, Limitation and Applications of Radioimmunoassay **Extraction techniques** General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.	**06 Hours**
UNIT-V **Hyphenated techniques** Introduction to hyphenated techniques and types of techniques Details of LC-MS, GC-MS, HPTLC-MS, MS/MS.	**08 Hours**

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.KSharma
2. Organic spectroscopy by Y.RSharma
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 spectroscopy by WilliamKemp
7. Quantitative Analysis of Drugs by D. C. Garrett
8. Spectrophotometric identification of Organic Compounds by Silverstein
9. Introduction to Spectroscopy by Donald Pavia
10. Spectroscopy of Organic compounds by P.S.Kalsi
11. Introduction to Spectroscopy by Donald Pavia
12. Spectroscopy of Organic compounds by P.S.Kalsi

BP812ET	**DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory)**	**45 Hours**

Scope:

This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective:

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. Recognize the components in dietary supplements and the application.
4. Acquaint with the regulatory and commercial aspects of dietary supplements including healthclaims.

Course content:

UNIT-I	
Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be	**07 Hours**

prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. 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	
UNIT-II **Phytochemicals as nutraceuticals**: Occurrence and characteristic features (chemical nature medicinal benefits) of following **Carotenoids**- α and β-Carotene, Lycopene, Xanthophylls, leutin **Sulfides:** Diallyl sulfides, Allyl trisulfide. **Polyphenolics**: Reservetrol **Flavonoids-** Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones **Prebiotics / Probiotics.:** Fructo oligosaccharides, Lacto bacillum **Phyto estrogens :** Isoflavones, daidzein, Geebustin, lignans **Tocopherols** Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats,Wheat bran, rice bran, sea foods, coffee, tea and the like.	**15 Hours**
UNIT-III **Introduction to free radicals:** Free radicals, reactive oxygen species,production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. Dietary fibres and complex carbohydrates as functional food ingredients.	**07 Hours**
UNIT-IV **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. **Antioxidants:** Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defense, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. Functional foods for chronic disease prevention.	**10 Hours**

UNIT-V Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. Regulatory Aspects; FSSAI,FDA, FPO,MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. Pharmacopoeial Specifications for dietary supplements and nutraceuticals.	**06 Hours**
References: 1. Dietetics by SriLakshmi 2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication. 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.Balchand Phyllis A.Balch2nd 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, NewYork. 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. AspenPress. 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 andFebiger	

BP 813 **PW PROJECT WORK** 150 **Hours**

A] Selection of the Project Topic

All the students shall undertake a project under the supervision of a teacher and submit a report. The project can be based on Lab oriented (small part of original research work) Study / Survey oriented or Computational studies or oriented. / Review topic/ Extension of Practice school work etc., based on Current Trends in Pharmaceutical science. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & hard bound copy not less than 25 pages).

The internal and external examiner appointed for evaluation of the project shall be approved teachers of SPPU /Industrial Experts appointed by Principal of the respective institute. 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

B] **Evaluation of Dissertation Book:**

Objective(s) of the work done	15Marks
Methodology adopted	20Marks
Results and Discussions	20Marks
Conclusions and Outcomes	20Marks
Total	75**Marks**

C] Evaluation of Presentation:

Presentation of work	25Marks
Communication skills	20Marks
Question and answer skills	30Marks
Total	75**Marks**

Explanation: All the students should be evaluated thoroughly based on their performance in the Laboratory /Literature work and presentation done as individual student under given criteria.