Shri Rawatpura Sarkar University, Raipur

Examination Scheme & Syllabus

For

BACHELOR IN PHARMACY

SEMESTER -VIII

(Effective from the session: 2019-20)

Faculty of Pharmacy
Shri Rawatpura Sarkar University, Raipur
BACHELOR OF PHARMACY
SEMESTER -VIII
Examination Scheme
(Effective from the session: 2019-20)

Sr. No.	Subject Code	Name of the Course with PCI code	Internal assessment								End semester exams			Total Marks
			TA	Sessional exams			Teaching hours per week			Credit				
				CT	Duration	Total	L	T	P		Marks		Duration	
1	BPH801T	Biostatistics and Research Methodology – Theory	10	15	1 Hrs	25	3	1		4	75	25	3 Hrs	100
2	BPH802T	Social and Preventive Pharmacy – Theory	10	15	1 Hrs	25	3	1		4	75	25	3 Hrs	100
3	BPH803ET	Pharmaceutical Marketing –Theory	10 + 10	15 + 15	1 Hrs + 1 Hrs	25 + 25	3 + 3	1 + 1		4 + 4	75+75	25+25	3+3 Hrs	100+ 100
4	BPH804ET	Pharmaceutical Regulatory Science – Theory												
5	BPH805ET	Pharmacovigilance – Theory												
6	BPH806ET	Quality Control and Standardizations of Herbals –Theory												
7	BPH807ET	Computer Aided Drug Design – Theory												
8	BPH808ET	Cell and Molecular Biology – Theory												
9	BPH809ET	Cosmetic Science – Theory												
10	BPH810ET	Experimental Pharmacology – Theory												
11	BPH811ET	Advanced Instrumentation Techniques – Theory												
12	BPH812PW	Project Work	--	--	--	--	6				150	--	4 Hrs	150
			40	60	4		22				450	100	16	550

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<table>
<tr><td>Course Title</td><td colspan="5">Biostatistics and Research Methodology – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH801T</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2" rowspan="2">Total marks in the end semester: 75
Minimum of class tests to be conducted: 02</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of the course the student shall be able to
• Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
• Know the various statistical techniques to solve statisticalproblems
• Appreciate statistical techniques in solving theproblems.</td></tr>
<tr><td>Course Contents</td><td colspan="6">Unit-I 10 Hours
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
Unit-II 10 Hours
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
Unit-III 10Hours
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,</td></tr>
</table>

	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, variousphases. **Unit-IV** **8 Hours** 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 **Unit-V** **7Hours** **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
Course Outcomes	▪ Study on various methodologies like Mean, Median, mode, SD, ANOVA, Chi square test, T test, F Test. 2 ▪ The students will understand the concept of research, its types, need, objectives and indications. ▪ The students should know the method of selecting the research problem and research proposal. ▪ The students should know the in-depth knowledge of tools and methods of literature survey. ▪ They should know the importance and techniques of documentation. ▪ The students should able to write the research report and paper. The thesis writing skill should be acquired by the students. ▪ The students should know how to apply for the research publication. ▪ The students should understand the proper oral presentation skill. ▪ The students should know the calculation of cost analysis of the project. ▪ The students should know different methods of experimental design. ▪ The students should have through knowledge of various methods of statistics, descriptive data analysis. ▪ The students should know the different measures, parameters and tests for inferential data analysis.

Text Books	1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork. 2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
Reference Books	1. Design and Analysis ofExperiments –PHI Learning PrivateLimited, R. Pannerselvam, 2. Design and Analysis of Experiments–Wiley Students Edition, Douglas and C. Montgomery

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<table>
<tr><td>Course Title</td><td colspan="5">Social and Preventive Pharmacy – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH802T</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td><td colspan="2">Minimum of class tests to be conducted: 02</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="6">After the successful completion of this course, the student shall be able to:
• Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country andworldwide.
• Have a critical way of thinking based on current healthcaredevelopment.
• Evaluate alternative ways of solving problems related tohealth and pharmaceutical issues</td></tr>
<tr><td>Course Contents</td><td colspan="6">UnitI 10 Hours

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

Unit II 10 Hours

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

Unit III 10 Hours

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</td></tr>
</table>

	programme, National programme for control of blindness, Pulse polio programme. **Unit IV** **08 Hours** 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 **Unit V** **07 Hours** 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.
Course Outcomes	Students will be able to understand the general measures and strategies to be followed in social and preventive pharmacy.
Text Books	1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEEPublications 2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, SahaIndranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications 3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6thEdition, 2014, ISBN: 9789351522331, JAYPEEPublications
Reference Books	1. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications 2. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOTPUBLISHERS. 3. Community Pharmacy Practice, Ramesh Adepu, BSP publishers,Hyderabad

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<table>
<tr><td>Course Title</td><td colspan="5">Pharmaceutical Marketing – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH803ET</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td><td colspan="2">Minimum of class tests to be conducted: 02</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="6">The course aim is to provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.</td></tr>
<tr><td>Course Contents</td><td colspan="6">
UnitI 10 Hours

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.

UnitII 10 Hours

Product decision:

Meaning, Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packagingand labeling decisions, Product management in pharmaceutical industry.

UnitIII 10 Hours

Promotion:

Meaning and 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

UnitIV 10 Hours

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriatechannel, conflict in channels, physical distribution management: Strategic importance, tasks in
</td></tr>
</table>

	physicaldistribution management. **Professional sales representative (PSR):** Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR. **UnitV** **10 Hours** **Pricing:** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issuesin 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; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.
Course Outcomes	Study on accounting, marketing, principles, economy, trading procedures.
Text Books	1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, NewDelhi 2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, NewDelhi. 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 (IndiaEdition)
Reference Books	1. Ramaswamy, U.S &Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, NewDelhi. 2. Shanker, Ravi: Service Marketing, Excell Books, NewDelhi 3. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

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<table>
<tr><td>Course Title</td><td colspan="5">Pharmaceutical Regulatory Science – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH804T</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td><td colspan="2">Minimum of class tests to be conducted: 02</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="6">Upon completion of the subject student shall be able to;

1.Know about the process of drug discovery anddevelopment

2.Know the regulatory authorities and agencies governing the manufacture andsale ofpharmaceuticals

3.Know the regulatory approval process and their registration in Indianand internationalmarkets</td></tr>
<tr><td>Course Contents</td><td colspan="6">Unit I 10Hours

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.

Unit II 10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA /ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III 10Hours

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.</td></tr>
</table>

	Unit IV **08Hours** **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 **Unit V** **07Hours** **Regulatory Concepts** Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book
Course Outcomes	Current practice of GMP, GLP in drug regulatory affairs, Know about the concept of QMS and good distribution practices
Text Books	1. Drug Regulatory Affairs by SachinItkar, Dr. N.S. Vyawahare, NiraliPrakashan. 2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berryand Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health carePublishers. 3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the PharmaceuticalSciences,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, DavidMantus.
Reference Books	1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series,Vol.143 2. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K.Adams 3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P.Ognibene 4. Drugs: From Discovery to Approval, Second Edition By RickNg

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<table>
<tr><td>Course Title</td><td colspan="5">Pharmacovigilance – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH805T</td><td>Total theory periods: 45 Hr’s</td><td>Total Tutorial periods: 15</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td colspan="2">Total marks in the end semester: 75</td></tr>
<tr><td>3</td><td>1</td><td></td><td>4</td><td colspan="2">Minimum of class tests to be conducted: 02</td></tr>
<tr><td>Prerequisites</td><td colspan="6">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="6">At completion of this paper it is expected that students will be able to
Why drug safety monitoring isimportant?
History and development ofpharmacovigilance
National and international scenario ofpharmacovigilance
Dictionaries, coding and terminologies used inpharmacovigilance
Detection of new adverse drug reactions and theirassessment
International standards for classification of diseases anddrugs
Adverse drug reaction reporting systems and communication inpharmacovigilance
Methods to generate safety data during pre-clinical, clinical and post approval phases of drugs’ life cycle
Drug safety evaluation in paediatrics, geriatrics, pregnancy andlactation
Pharmacovigilance Program of India(PvPI)
ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilanceplanning
CIOMS requirements for ADRreporting
Writing case narratives of adverse events and theirquality.</td></tr>
<tr><td>Course Contents</td><td colspan="6">Unit I 10 Hours
Introduction to Pharmacovigilance
History and development ofPharmacovigilance
Importance of safety monitoring ofMedicine</td></tr>
</table>

- WHO international drug monitoringprogramme
- Pharmacovigilance Program ofIndia(PvPI)

Introduction to adverse drug reactions

- Definitions and classification ofADRs
- Detection andreporting
- Methods in Causalityassessment
- Severity and seriousnessassessment
- Predictability and preventabilityassessment
- Management of adverse drugreactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication relatedevents
- Regulatoryterminologies

Unit II **10 hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification ofdrugs
- International classification ofdiseases
- Daily defineddoses
- International Non proprietary Names fordrugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reactionterminologies
- MedDRA and Standardised MedDRAqueries
- WHO drugdictionary
- Eudravigilance medicinal productdictionary

Information resources in pharmacovigilance

- Basic drug informationresources
- Specialised resources forADRs

Establishing pharmacovigilance programme

- Establishing in ahospital
- Establishment & operation of drug safety department inindustry
- Contract Research Organisations(CROs)
- Establishing a nationalprogramme

Unit III **10Hours**

Vaccine safety surveillance

- VaccinePharmacovigilance
- Vaccinationfailure
- Adverse events followingimmunization

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and caseseries
- Stimulatedreporting
- Active surveillance – Sentinel sites, drug event monitoring andregistries
- Comparative observational studies – Cross sectional study, case control study and cohortstudy
- Targeted clinicalinvestigations

Communication in pharmacovigilance

- Effective communication inPharmacovigilance
- Communication in Drug Safety Crisismanagement
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

UnitIV **8Hours**

Statistical methods for evaluating medication safety data

Safety data generation

- Pre clinical phase
- Clinical phase

	Post approvalphase **ICH Guidelines for Pharmacovigilance** Organization and objectives ofICH Expeditedreporting Individual case safetyreports Periodic safety updatereports Post approval expeditedreporting Pharmacovigilanceplanning Good clinical practice in pharmacovigilancestudies **Unit V** **7hours** **Pharmacogenomics of adverse drug reactions Drug safety evaluation in special population** Paediatrics Pregnancy andlactation Geriatrics **CIOMS** CIOMS WorkingGroups CIOMS Form **CDSCO (India) and Pharmacovigilance** D&C Act and ScheduleY Differences in Indian and global pharmacovigilancerequirements
Course Outcomes	• Students will gain knowledge on monitoring, analysing and reporting of adverse drug reactions. • Critically discuss issues associated with global pharmacovigilance. Analyse the stages of drug development in terms of drug safety assessment and benefit risk. Critically explain the strengths and weakness of pharmacovigilance reporting systems.

Text Books	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 BartlettPublishers. 3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, WileyPublishers. 4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, WileyPublishers. 5. An Introduction to Pharmacovigilance: Patrick Waller,WileyPublishers. 6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& BartlettPublishers.
Reference Books	1. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,WileyPublishers. 2. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C.Nahata 3. National Formulary ofIndia 4. Text Book of Medicine by YashpalMunjal 5. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

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<table>
<tr><td>Course Title</td><td colspan="5">Quality Control and Standardizations of Herbals – Theory BP806ET</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH806ET</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td rowspan="2">Total marks in the end semester: 75</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the subject student shall be able to;
1.know WHO guidelines for quality control of herbaldrugs
2.know Quality assurance in herbal drugindustry
3.know the regulatory approval process and their registration in Indianand internationalmarkets
4.appreciate EU and ICH guidelines for quality control of herbaldrugs</td></tr>
<tr><td>Course Contents</td><td colspan="5">UnitI 10 hours
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
UnitII 10 hours
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.
Unit III 10 hours
EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines
UnitIV 08 hours
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.</td></tr>
</table>

	UnitV **07 hours** 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
Course Outcomes	• Students be able to understand the types of standardisation and methods of HPTLC for validation. • Prepare, label & evaluate herbal/TSM formulations. ✓ Evaluate marketed cosmetic & nutraceutical formulations ✓ Conduct pre-formulation parameters & understand underlying rationale ✓ Conduct in vitro assays for correlation with biological efficacy
Text Books	1. Pharmacognosy by Trease andEvans 2. Pharmacognosy by Kokate, Purohit andGokhale 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/TraditionalMedicinal Products, 6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluationof Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
Reference Books	1. 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. 2. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use ofHerbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998. 3. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rdedn. World Health Organization, Geneva,1981. 4. WHO. Quality Control Methods for Medicinal Plant Materials. World Health

	Organization, Geneva,1999. 5. WHO. WHO Global Atlas of Traditional, Complementary andAlternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva,2005. 6. WHO. Guidelines on Good Agricultural and Collection Practices (GACP)for Medicinal Plants. World Health Organization, Geneva,2004.

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<table>
<tr><td>Course Title</td><td colspan="5">Computer Aided Drug Design – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH807ET</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td>Total marks in the end semester: 75</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td><td></td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the course, the student shall be able to understand
• Design and discovery of leadmolecules
• The role of drug design in drug discoveryprocess
• The concept of QSAR anddocking
• Various strategies to develop new drug likemolecules.
• The design of new drug molecules using molecular modelingsoftware</td></tr>
<tr><td>Course Contents</td><td colspan="5">UNIT-I 10 Hours

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
UNIT-II 10 Hours
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.

UNIT-III 10 Hours
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.</td></tr>
</table>

	UNIT-IV **08 Hours** **Informatics & Methods in drug design** Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases. **UNIT-V** **07 Hours** **Molecular Modeling:** Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.
Course Outcomes	• Students gain knowledge in QSAR to work on basis of drug discovery. • History of Computers in Pharmaceutical Research and Development • Computational Modeling of Drug Disposition • Computers in Preclinical Development • Optimization Techniques in Pharmaceutical Formulation • Computers in Market Analysis • Computers in Clinical Development • Artificial Intelligence (AI) and Robotics • Computational fluid dynamics (CFD)
Text Books	1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak PressBaltimore. 2. Martin YC. "Quantitative Drug Design" Dekker, NewYork. 3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, NewYork. 4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger. 5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
Reference Books	1. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, NewYork. 2. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press. 3. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" WrightBoston.

	4. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press NewYork.

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<table>
<tr><td>Course Title</td><td colspan="5">Cell and Molecular Biology – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH808ET</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td rowspan="2">Total marks in the end semester: 75</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the subject student shall be able to;
Summarize cell and molecular biologyhistory.
Summarize cellular functioning andcomposition.
Describe the chemical foundations of cellbiology.
Summarize the DNA properties of cellbiology.
Describe protein structure andfunction.
Describe cellular membrane structure andfunction.
Describe basic molecular geneticmechanisms.
Summarize the CellCycle</td></tr>
<tr><td>Course Contents</td><td colspan="5">UnitI 10Hours
a) Cell and Molecular Biology: Definitions theory and basics andApplications.
b) Cell and Molecular Biology: History andSummation.
c) Theory of the Cell? Properties of cells and cellmembrane.
d) Prokaryotic versusEukaryotic
e) CellularReproduction
f) Chemical Foundations – an Introduction and Reactions(Types)
UnitII 10 Hours
a) DNA and the Flow of MolecularStructure
b) DNAFunctioning
c) DNA andRNA</td></tr>
</table>

	d) Types ofRNA e) Transcription andTranslation **UnitIII** **10 Hours** a) Proteins: Defined **and** AminoAcids c) ProteinStructure Regularities in ProteinPathways d) CellularProcesses e) Positive Control and significance of ProteinSynthesis **UnitIV** **08 Hours** a) Science ofGenetics b) Transgenics and Genomic Analysis c) Cell Cycleanalysis d) Mitosis andMeiosis e) Cellular Activities andCheckpoints **UnitV** **07 Hours** a) Cell Signals:Introduction b) Receptors for CellSignals c) Signaling Pathways:Overview d) Misregulation of SignalingPathways e) Protein-Kinases:Functioning
Course Outcomes	Students able to know cell structure, functions, composition, DNA, function in cells.
Text Books	1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, BlackwellScientific publications, OxfordLondon. 2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors,Delhi. 3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hilledn. 4. Malcolm Harris, Balliere Tindall and Cox: PharmaceuticalMicrobiology. 5. Rose: Industrial Microbiology.

	6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed.Japan 7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher andDistribution.
Reference Books	1. Peppler: MicrobialTechnology. 2. Edward: Fundamentals ofMicrobiology. 3. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan,Delhi 4. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company 5. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press WashingtonD.C. 6. RA Goldshy et. al., : KubyImmunology.

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<table>
<tr><td>Course Title</td><td colspan="5">Cosmetic Science – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH809ET</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td rowspan="2">Total marks in the end semester: 75</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the subject student shall be able to;

Key ingredients used in cosmetics and cosmeceuticals.

Key building blocks for various formulations.

Various key ingredients and basic science to develop cosmetics and cosmeceuticals

Scientific knowledge to develop cosmetics and with desired Safety, stability, and efficacy.</td></tr>
<tr><td>Course Contents</td><td colspan="5">UNITI 10Hours

Classification of cosmetic and cosmeceutical products

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.

UNITII 10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream their relative skinsensory, advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioners,antidandruff 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</td></tr>
</table>

	gums, sensitive teeth. Teeth whitening, Mouthwash. **UNITIII** **10 Hours** 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**.** **UNITIV** **08 Hours** Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs. Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combingproperties Soaps,and syndet bars. Evolution and skin beneits. **UNITV** **07 Hours** 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
Course Outcomes	. • Study on various cosmetic ingredients. Analysis of individual cosmetic products and stability studies and toxicological studies of cosmetic products. • State the correct use of various equipments in Pharmaceutics laboratory relevant to cosmetics. ✓ Perform formulation, evaluation and labelling of cosmetics like moisturising cream, vanishing cream etc. ✓ Perform formulation, evaluation of eye cosmetics, nail lacquer & shampoo. ✓ Perform formulation, evaluation & labelling of shaving cream, after shave & baby products.

	✓ Describe use of ingredients in formulation and category of formulation. ✓ Prepare labels as per regulatory requirements.
Text Books	1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, GeorgeGodwin.
Reference Books	1) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd.,Delhi.

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<table>
<tr><td>Course Title</td><td colspan="5">Experimental Pharmacology – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH810ET</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td rowspan="2">Total marks in the end semester: 75</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the course the student shall be able to,
• Appreciate the applications of various commonly used laboratoryanimals.
• Appreciateanddemonstrate the various screening methods used in preclinical research
• Appreciate and demonstrate the importance of biostatistics andresearchmethodology
• Design and execute a research hypothesisindependently</td></tr>
<tr><td>Course Contents</td><td colspan="5">Suggested Title:PHARMACOLOGICAL SCREENING METHODS
Unit –I 08 Hours
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 mutantanimals.
Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection
and euthanasia.
Unit –II 10 Hours
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 thestudy.
b. Study of screening animal modelsfor
Diuretics, nootropics, anti-Parkinson’s,antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic,</td></tr>
</table>

	antiparkinsonism, alzheimer's disease **Unit –III** **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics **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 **Unit –V** **05 Hours** **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 of data
Course Outcomes	• Candidates understand the pharmacokinetics and dynamic reactions of drug and its importance in treatment of disease and its ADR • Understanding the in vivo and in vitro experiments, use of software for the study of preclinical experiments. • Understanding the PA2 and PD2 value of drugs using isolated tissue preparations. • Understanding the brief idea about statistics, its applications in experimental pharmacology. • Understanding to solve problems using various statistical tests.
Text Books	1. Fundamentals of experimental Pharmacology-byM.N.Ghosh 2. Hand book of ExperimentalPharmacology-S.K.Kulakarni 3. CPCSEA guidelines for laboratory animalfacility.

Reference Books	1. Drug discovery and Evaluation by VogelH.G. 2. Drug Screening Methods by Suresh Kumar Gupta and S. K.Gupta 3. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

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<table>
<tr><td>Course Title</td><td colspan="5">Advanced Instrumentation Techniques – Theory</td></tr>
<tr><td>Course Code</td><td colspan="4">BPH811ET</td><td>Total Practical periods: 04 Hrs. / week</td></tr>
<tr><td rowspan="2">Course Credits</td><td>L</td><td>T</td><td>P</td><td>TC</td><td rowspan="2">Total marks in the end semester: 75</td></tr>
<tr><td></td><td></td><td>4</td><td>2</td></tr>
<tr><td>Prerequisites</td><td colspan="5">Basic fundamentals studied in previous class in B. Pharm</td></tr>
<tr><td>Course Objectives</td><td colspan="5">Upon completion of the course the student shall be able to
• understand the advanced instruments used and its applications in druganalysis
• understand the chromatographic separation and analysis ofdrugs.
• understand the calibration of various analyticalinstruments
know analysis of drugs using various analyticalinstruments.</td></tr>
<tr><td>Course Contents</td><td colspan="5">UNIT-I 10 Hours
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
UNIT-II 10 Hours
Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (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.
UNIT-III 10 Hours
Calibration and validation-as per ICH and USFDA guidelines
Calibration of following Instruments
Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,</td></tr>
</table>

	Fluorimeter, Flame Photometer, HPLC and GC **UNIT-IV** **08 Hours** **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 **UNIT-V** **07 Hours** **Hyphenated techniques**-LC-MS/MS, GC-MS/MS, HPTLC-MS.
Course Outcomes	. The course will help in imparting theoretical aspects, instrumentation and application of various techniques like spectroscopy, chromatography etc To understand the fundamentals on conventional analytical methods of drug analysis used in laboratories and also the basic principles of various sophisticated analytical techniques. □ To know the proper procedures and regulations for safe handling and use of chemicals and instruments. □ To understand the applications of various analytical methods of drugs & pharmaceuticals as per the standards. □ To acquire sufficient skill in handling of equipment's/procedures for estimation of pharmaceuticals. □ To have a thorough theoretical and practical understanding of advanced analytical instruments. □ To develop new technologies and methods for measuring qualitative as well as quantitative analysis of various pharmaceutical compounds from organic, inorganic and herbal origin with cost effective approach. □ Able to communicate scientific results in writing and in oral presentation. □ Able to design and carry out scientific experiments with accurate record of results of such experiments. □ Able to work in a team so as to involve in interdisciplinary research projects.
Text Books	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
Reference Books	1. Organic Chemistry by I. L.Finar 2. Organic spectroscopy by WilliamKemp 3. Quantitative Analysis of Drugs by D. C.Garrett 4. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D.Sethi 5. Spectrophotometric identification of Organic Compounds bySilverstein