

# **ACADEMIC PROGRAMME GUIDE**

## **BACHELOR OF SCIENCE**

**Batch 2018**



**Chitkara University School of Basic Sciences  
Chitkara University, Himachal Pradesh, India**

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## 1. General Information

The academic program guide is a comprehensive document detailing course scheme, associated credits per course and the distribution of each course in lecture, tutorial and practical hours. It also details the eligibility criteria for admission, for award of degree, the assessment and evaluation procedures along-with a glimpse of the pedagogical aspects of the programs. This guide is to be used in association with the academic regulations of the university to make a complete rule set. The course schemes given in this document are approved by respective Board of Studies and the Academic Council of Chitkara University, Himachal Pradesh.

## 2. Eligibility for Admission

The student seeking admission in B.Sc. program should have minimum 60% marks in 12<sup>th</sup> grade (Science) or equivalent exam with Physics, Chemistry, Biology or Mathematics. The admission is based purely on merit. During admission process, the university follows reservation policy as decided by the State.

## 3. Duration and Stages

The duration of the B.Sc. program is three years - divided into 6 semesters. University conducts end term examination at the end of each semester.

## 4. Rules for attendance

Minimum attendance criteria of 75% are mandatory in each course for appearing in End Semester Examinations. The Program being highly rigorous, all the students are expected to show utmost regularity in attendance. Even a day's absence is detrimental to student's interest. Therefore, University's requirements in this regard are very stringent. The university expects its students to be regular in attending the classes. 75% attendance (of all held sessions – lectures, tutorials, project work) is compulsory in a course in order to be eligible to appear for End Term Examination.

## 5. Course Handouts

Course handout that supports, expands on, organizes or otherwise provides follow up to the course. Course handouts are be very successful because participants can use them to remember what they have learned, to extend their knowledge further by reading material not covered in the course and as a basis for their work in cascading learning to their colleagues.

## 6. Pedagogical Aspects

The structural layout of the program and its courses requires that each course be divided in lecture, tutorial and practical sessions.

**Lecture sessions:** Lectures are delivered by traditional- chalk board method, supplemented by modern Information Communication Technology (ICT) methods. The students are

encouraged to ask questions and involve in group discussion to the extent allowed by the teacher.

**Tutorial Sessions:** The tutorial sessions are small groups of students interacting with the teacher, solving application oriented analytical problems. The tutorial sessions are very interactive and inculcate problem solving skills in the students.

**Lab / Practical Sessions:** During lab / practical sessions, the students work on prescribed list of experiments and do what they have learnt in the lecture / tutorial sessions.

## 7. Assessment and Evaluation

The examinations have two segments:

- (a) **Internal Assessment:** It may comprise quiz tests, seminars, class participation and mid semester examination.
- (b) **External End Semester Examination:** at the end of each semester.

There will be one mid semester examination conducted during the mid of the semester and two quiz tests one before the mid semester examination and one after the mid semester examination. Controller of Examinations conducts mid semester and the end semester examination. Weightage for various evaluation components in each course of the program is as below:

Sr. No.	Evaluation Component	Weightage
1	Quiz	20
2	Mid Semester Exam	30
3	End Semester Exam	50

The end term examination for practical courses includes conduct of experiment and a viva voce.

Sr. No.	Evaluation Component	Marks
1	Internal exam and viva	30
2	External exam and viva	70

Grade points for every grade are as follows:

Marks Range	Grade	Grade Weightage	Qualitative Meaning
80 - 100	O	10	Outstanding
70-79	A+	9	Excellent
60-69	A	8	Very Good
55-59	B+	7	Good
50-54	B	6	Above Average
45-49	C	5	Average

40-44	P	4	Pass
0-39	F	0	Fail
	AB		Absent

If the student is detained from appearing in the end term examination because of the shortage of attendance in the regular semester or is absent in the end term examination, his grade in that subject is 'AB', till he/she appears again in the end term exam and obtains a new grade.

## 8. Course Scheme: B.Sc. (Pharmaceutical Chemistry) Program Batch 2018

**Program Name:** Bachelor of Science (Pharmaceutical Chemistry)

**Duration:** 3 years

**Program Overview:** Pharmaceutical Chemistry as academic discipline makes for an enriching learning experience as it perfectly combines technology and health care system. The profession of Pharmaceutical Chemistry has transformed into a hub for the "Global Healthcare" and evolved as a multidisciplinary, multifaceted curriculum. Learning and working in harmony with other members of health care are the immediate needs for the ideal role and social relevance in the health care system of our country. So, the academic system has been framed taking into consideration the responsibility of undergraduate students to meet the demands of hi-tech pharmaceutical industry, at the same time ensuring that they confidently serve the requirements of patient care and pharmacy practice. Conscious efforts to inculcate research aptitude in its students through elective research projects to keep them abreast of the requirements of the industry.

**Program Objectives:** Some of the main objectives of our B.Sc. (Pharmaceutical Chemistry) program are as follows:

- To produce graduates with strong fundamental concepts and high technical competence in pharmaceutical sciences who shall be able to use these tools in pharmaceutical industry where ever necessary for success.
- To provide students with strong and well-defined concepts in the various fields of pharmacy i.e., pharmaceutics, microbiology, pharmaceutical chemistry, pharmacology, operation management, quality assurance and pharmacognosy according to the requirement of pharmaceutical industries and society.
- To promote the development of trained human resource in pharmaceutical sciences with highly professional and ethical attitude, effective skills to work in a team with a multi-disciplinary approach.
- To develop overall personality and character with team spirit, professionalism, integrity and moral values with the support of social pharmacy and health sciences.

**Program Outcomes (POs):** Main POs of our B.Sc. (Pharmaceutical Chemistry) program are as follows:

- Ability to acquire knowledge of fundamentals of health principals and their applications in the area of pharmaceutical sciences.

- (b) Identify, formulate, research literature, and analyze complex health problems reaching substantiated conclusions using principles of natural, herbal and allopathic science.
- (c) Use research-based knowledge and research methods including design of experiments, analysis and interpretation of data to provide valid conclusions.
- (d) An understanding of professional, societal and legal responsibility related to pharmaceutical industry.
- (e) An understanding of the impact of pharmacy profession in environment & societal context and demonstrate the need for sustainability.
- (f) Development of an aptitude for lifelong learning as well as continuous professional development.
- (g) Function effectively as an individual, and as a member or leader in diverse teams, and in multidisciplinary environment.

**Program Specific Outcomes (PSOs):** Main PSOs of our B.Sc. (Pharmaceutical Chemistry) program are as follows:

- (a) Understanding of basic principles of pharmaceutical chemistry, pharmaceutics, pharmacology and pharmacognosy for drug discovery and formulation development.
- (b) Understanding of the formulation parameters in manufacturing of a dosage form, storage, packaging and dispensing of dosage forms.
- (c) Understanding of basics principles for drug analysis through conventional methods and modern sophisticated instruments.
- (d) Understanding of drug chemistry and its structure for synthesis of drug and drug designing using modern software.
- (e) Understanding of crude drug, its identification, extraction and purification for its medicinal value.
- (f) Understanding of documentation, quality control and quality assurance of all the processes and pharmaceutical formulations.
- (g) Understanding of novel drug delivery systems, molecular modeling, analytical tools, pharmaceutical management etc., as per the need of industry and future prospects.
- (h) Perform research on various medical aspects and implement the pharmaceutical knowledge in formulating the best suitable dosage form to provide high quality medicines to the society.

**Placement Opportunities:** The Bachelor of Science (Pharmaceutical Chemistry) provides ample opportunity to a graduate to join various areas in pharmaceutical industry set up as well as in a hospital pharmacy support. The level of appointment and compensation there upon may depend upon the job profile and need for further additional post graduate specialization in specific areas. The possible positions are:

- (a) Research & Formulation Development Executive: Development of new formulations.
- (b) Production Executive: Managing and supervising production of formulations.
- (c) Project Executive (New Products): Coordinating the research, production and marketing activities in a Pharmaceutical organization, deciding as to what and how to develop a new product and plan production and marketing activity as per available capacity.
- (d) Project Executive (New Plant): Coordinating & erection, installation commissioning of production in a new plant / facility and ensuring that all installation and procedures are as per compliance norms laid out by regulatory agencies.

- (e) Executive (Administration & Finance)/ Management Trainee: In a pharmaceutical organization.
- (f) Executive /Asth. Manager, Regulatory affairs: Helping the research team to compile drug master files for new drug products for registration and approval with the food & Drug authority of different countries.
- (g) Sales and Marketing: A career in marketing starting as a sales person and then diversifying into product management, training and market research.

### 9. Course Scheme: B.Sc. (Pharmaceutical Chemistry) Year I

Semester I			
Course Code	Title of the Course	Hours (L+T+P)	Credit
BPL3101	Introduction to Pharmaceutical Sciences	4+0+0	4
BPL3103	Pharmaceutical Chemistry-I	4+0+0	4
BPP3103	Pharmaceutical Chemistry-I Practical	0+0+4	2
BPL3105	Physical Chemistry	4+0+0	4
BPL3107	Industrial Safety and Environmental Sciences	4+0+0	4
	Total	20 hrs	18

BPPR3109	Project-I	20 hrs	10
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Semester II			
Course Code	Title of the Course	Hours (L+T+P)	Credit
BPL3102	Chemistry of Natural Products (CNP)	4+0+0	4
BPL3104	Physical Pharmaceutics-I	4+0+0	4
BPP3104	Physical Pharmaceutics-I Practical	0+0+4	2
BPL3106	Pharmaceutical Microbiology	4+0+0	4
BPL3108	Pharmaceutical Analysis-I	4+0+0	4
	Total	20 hrs	18

BPPR3110	Project-II	20 hrs	10
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**Total credits of 1<sup>st</sup> year Courses: 28+28 = 56**

### 10. Course Scheme: B.Sc. (Pharmaceutical Chemistry) Year II

Semester III			
Course Code	Title of the Course	Hours (L+T+P)	Credit
BPL3211	Pharmaceutical Chemistry-II (Organic	4+0+0	4

	Chemistry)		
BPL3213	Physical Pharmaceutics-II	4+0+0	4
BPL3215	Pharmaceutical Operation-I	4+0+0	4
BPP3215	Pharmaceutical Operation-I Practical	0+0+4	2
BPL3217	Pharmaceutical Regulatory Affairs	4+0+0	4
	Total	20 hrs	18

BPPR3219	Project-III	20 hrs	10
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Semester IV			
Course Code	Title of the Course	Hours (L+T+P)	Credit
BPL3212	Physiology and Pharmacology-I	4+0+0	4
BPP3212	Physiology and Pharmacology-I Practical	0+0+4	2
BPL3214	Biochemistry	4+0+0	4
BPL3216	Pharmaceutical Process-I	4+0+0	4
BPL3218	Industrial Pharmacy & Packaging Technology	4+0+0	4
	Total	20 hrs	18

BPPR3220	Project-IV	20 hrs	10
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**Total credits of 2<sup>nd</sup> year Courses: 28+28 = 56**

### 11. Course scheme: B.Sc. (Pharmaceutical Chemistry) Year III

Semester V			
Course Code	Title of the Course	Hours (L+T+P)	Credit
BPL3321	Pharmaceutical Quality Assurance	4+0+0	4
BPL3323	Medicinal Chemistry-I	4+0+0	4
BPP3323	Medicinal Chemistry-I Practical	0+0+4	2
BPL3325	Pharmaceutical Process-II	4+0+0	4
BPL3327	Pharmaceutical Analysis-II	4+0+0	4
BPP3327	Pharmaceutical Analysis-II Practical	0+0+4	2
	Total	24 hrs	20

BPPR3329	Project-V	20 hrs	10
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Semester VI			
Course Code	Title of the Course	Hours (L+T+P)	Credit
BPL3322	Dosage Form Design (DFD)	4+0+0	4
BPP3322	Dosage Form Design (DFD) Practical	0+0+4	2
BPL3324	Pharmaceutical Operation-II	4+0+0	4
BPL3326	Pharmaceutical Operation Management	4+0+0	4
BPL3328	Medicinal Chemistry-II	4+0+0	4
BPP3328	Medicinal Chemistry-II Practical	0+0+4	2
	Total	24 hrs	20

  

BPPR3330	Project-VI	20 hrs	10
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**Total credits of 3<sup>rd</sup> year Courses: 30+30 = 60**

## 12. Course Syllabus: B.Sc. (Pharmaceutical Chemistry) Year I

### Semester I

<b>BPL3101</b>	<b>Introduction to Pharmaceutical Sciences</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### Course Learning Outcomes (CLOs):

- CLO1: To understand various types of routes for administration of drugs.
- CLO2: To understand formulation and preparation of various types of dosage forms.
- CLO3: To understand basics of quality control and know about various techniques of analysis.

Orientation and historical background of pharmacy profession: Pharmacy as a career, Pharmacy Profession: History of Pharmacy in India, Pharmaceutical education in India and abroad. Official books: Introduction to official compendia with emphasis on Indian pharmacopeias, British Pharmacopeias and United State Pharmacopeias. Routes of Drug Administration: Need for dosage forms, therapeutic consideration in dosage form designing. Routes of drug administration and dosage forms for oral, rectal, parenteral, subcutaneous, ocular, optic and nasal route. Introduction to different dosage forms, their classification with examples: Definitions of solid dosages form like powders and granules, dentifrices, capsules and tablets, liquid orals like solutions, aromatic waters, syrups, spirits, elixirs, glycerine, lotions, liniments, gargles, mouth washes, douches, draught preparation, sterile products like injectables, implants, ophthalmic formulations and semi solid products, solutions for external use- suppositories. Important terminologies in Pharmacy: Definitions and examples. Introduction to Quality Control: Significance of quantitative analysis in quality control, Different techniques of analysis.

#### Book (s) Recommended

- Allen LV, Popovich NG, Ansel HC. Pharmaceutical Dosage Forms and Drug Delivery. Lippincott Williams and Wilkins.

- Carter SJ. Cooper and Goon's Tutorial Pharmacy. CBS Publishers and Distributors.
- Carter SJ. Dispensing for Pharmaceutical Students. CBS Publishers and Distributors.
- Rowe R, Sheskey P, Quinn ME. Handbook of Pharmaceutical Excipients. Pharmaceutical Press.

<b>BPL3103</b>	<b>Pharmaceutical Chemistry-I</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand various concepts of acid-bases and buffers.
- CLO2: To understand about chemistry of various inorganic pharmaceutical agents.
- CLO3: To understand basics of various aromatic and heterocyclic compounds.

Acid-base concept and Buffers: Arrhenius concept, Bronsted Lowry concept and Lewis concept. Buffer action, buffer capacity and pharmaceutical applications of buffers. Gastrointestinal agents: Acidifying agents, antacids, cathartics, emetics and antimicrobial agents. Major Intra and extra cellular electrolytes: Major physiological ions, electrolytes used in replacement therapy, physiological acids-base balance, electrolytes used in acid-base therapy, electrolyte combination therapy. Essential and trace ions: Copper, zinc, chromium, manganese, molybdenum, selenium, sulphur and iodine. Miscellaneous inorganic pharmaceutical agents: Inhalants; respiratory stimulants, expectorants, poison and antidote and pharmaceutical aids. Aromatic Compounds: Structure and resonance of benzene, aromatic character, mechanism of electrophilic aromatic substitution, orientation effects in electrophilic substitution, nucleophilic aromatic substitution. Preparation, properties and actions of: Phenols, carboxylic acids, amines, diazonium salts, aryl halides and ketones. Poly nuclear aromatic hydrocarbons: Naphthalene, phenanthrene and anthracene. Heterocyclic compounds: Study of fundamentals of heterocyclics, nomenclature, methods of synthesis and important chemical reactions of the following: (a) Five-membered heterocycles: Furan, thiophene, pyrrole, thiazole, oxazole, imidazole, pyrazole, triazole and tetrazole; (b) Six-membered heterocycles: Pyridine, pyridazine, pyrimidine, pyrazine. Benz-fused heterocycles: Quinoline, isoquinoline, indole.

**Book (s) Recommended**

- Chaudhary NC, Gurbani NK. Pharmaceutical Chemistry 1. Vallabh Prakashan.
- Nadendla RR. Pharmaceutical Organic Chemistry (Part I). Vallabh Prakashan.
- Nadendla RR. Pharmaceutical Organic Chemistry (Part II). Vallabh Prakashan.

<b>BPP3103</b>	<b>Pharmaceutical Chemistry-I Practical</b>	<b>0-0-2</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO 1: Gain knowledge about various types of limit tests for impurities.
- CLO 2: Improve skills of qualitative analysis of pharmaceutical products.
- CLO 3: Gain hand on experience about tests for purity of pharmaceutical products.
- CLO 4: Understand the preparation of inorganic pharmaceutical products.
- CLO 5: Gain hand on experience on quantitative analysis of pharmaceutical products.

Limit tests for impurities in Pharmacopial compounds. Quantitative/Qualitative analysis: Assay of the following compounds will be done: solution of ammonia, boric acid, sodium bicarbonate, sodium carbonate, ferrous sulphate, strong and weak iodine solutions, copper sulphate, chlorinated lime, sodium chloride, ammonium chloride, sodium sulphate, calcium gluconate, magnesium sulphate, arsenic trioxide, bismuth oxychloride, and bismuth subnitrate.

**Book (s) Recommended:**

- Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry. The Athelone Press.
- Singh HK, Kapoor VK. Practical Pharmaceutical Chemistry. Vallabh Prakashan.

<b>BPL3105</b>	<b>Physical Chemistry</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand various concepts of laws of thermodynamics and Carnot cycle.
- CLO2: To understand about various types of colligative properties of solutions.
- CLO3: To understand basics of electrochemistry techniques and photochemistry laws.

Thermodynamics: Preliminary and definitions of systems, surrounding, macroscopic properties and state variables, thermodynamic equilibria, extensive and intensive properties, first law of thermodynamics, internal energy and first law, enthalpy of system, heat capacity, correlation between  $C_p$  and  $C_v$  for an ideal gas. Work done on reversible isothermal expansion of an ideal gas. Adiabatic expansion of an ideal gas, work of expansion, internal energy change and enthalpy change. Comparison of isothermal and adiabatic changes. Limitations of first law and need of second law. Cyclic process, Carnot cycle, definition of second law of thermodynamics, spontaneous process. Concept of entropy, entropy change accompanying change of phase, entropy changes in reversible and irreversible processes. Absolute entropy, determination of absolute entropy with the help of third law of thermodynamics. Applications of thermodynamics. Solutions: Solutions of liquids in liquids, ideal and real solutions, colligative properties of dilute solution, lowering of vapor pressure of non-volatile solute, osmosis and osmotic pressure in terms of chemical potential, Vant-Hoff equation for osmotic pressure of dilute solutions, elevation of boiling point and depression in freezing point by a non-volatile solute, determination of molar mass from vapor pressure lowering, osmotic pressure, boiling point elevation and freezing point depression, Solute distributing in immiscible solvent, distribution coefficient, conditions for validity of distribution law and the thermodynamic derivation, biological applications. Electrochemistry: Electrode potential, Nernst equation, standard potential, standard hydrogen electrode, reference electrodes, indicator electrodes. Potentiometry: Theoretical consideration, ion-selective electrodes, measurement of potential, location of the end point, equipment, analytical applications, differential curves, determination of  $K_{sp}$ , pH measurements, dead-stop titrations; pH meter, pH definition, equipment, applications. Kinetics: Reaction Rate: Rate and rate constant, order and molecularity, zero, first and second order reactions, half life time, integration of rate expressions, methods of determining order of a reaction, effect of temperature on reaction rates, Arrhenius equation. Concept of steady state approximation, activation energy, energy barrier. Collision and activated complex theory of bimolecular reactions. Catalysis: Characteristics of catalyzed reactions; definition of the terms, autocatalysis, negative catalysis, inhibitors, promoters, homogeneous and heterogeneous

catalysis, acid base catalysis and its mechanism, enzyme catalysis, Michaelis Menten equation, turn over number, the Line Weaver- Burk method. Photochemistry: Introduction, consequences of light absorption, the Jablonski diagram, Lambert Beer law, Grothus Draper law, the Stark-Einstein law of Photochemical equivalence, Quantum efficiency of quantum yield, Photochemical reaction.

**Book (s) Recommended:**

- Laidler KJ. Physical Chemistry with Biological Applications. Benjamin.
- Puri BR, Sharma LR, Pathania MS. Principles of Physical Chemistry. Vishal Publishing.
- Bahl BS, Tuli GD, Bahl A. Essentials of Physical Chemistry. S. Chand Publishers.

<b>BPL3107</b>	<b>Industrial Safety and Environment Sciences</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To gain knowledge about the environment and its allied problems.
- CLO2: To understand about industrial hazards and safety measures.
- CLO3: To understand effect of human population on environment.

Personal Basics and Chemical Safety: PPE, Compatibility Matrices, MSDS, Waste Management, Storage Concerns, Safety measures in handling and storage of chemicals, Fire chemistry and its control, Safety color codes of chemicals. Hazard Classification: Hazard Classification chemical, physical, mechanical, ergonomics, biological and noise hazards, Hazards from utilities like air, water, steam. Process Safety: Process Regulation Via Controls, Runaway Reactions, Vents and Valves, Licencing, Plant Design/Layout, Energetic Concerns (Explosions), Spill Clean-Up, Accident Analysis, Utilities Management, Safety in plant design and layout, Safety provisions in the factory act 1948, Indian explosive act 1884, ESI act 1948. Risk Management: Overall risk analysis, Methods for determining consequences effects: Effect of fire, Effect of explosion and toxic effect, Emergency Planning, First aids. Environmental Pollution: Definition; Causes, effects and control measures of air, water, soil, marine, noise, thermal, and nuclear pollution; Solid waste management, Role of an individual in prevention of pollution, Disaster management. Social Issues and the Environment: From unsustainable to sustainable development, Urban problems and related to energy, Water conservation, Rain water harvesting, Watershed management, Resettlement and rehabilitation of people, Environmental ethics, Climate change, global warming, acid rain, ozone layer depletion, nuclear accidents and holocaust, Wasteland reclamation, Consumerism and waste products, Acts (EPA, Water, Air, Wildlife and Forest conservation); Environmental legislation. Human Population and the Environment: Population growth and explosion, Environment and human health, Human Rights, Value Education, HIV / AIDS, Family, Women and Child Welfare, Role of Information Technology in Environment and Human Health.

**Book (s) Recommended:**

- Blake RP. Industrial Safety. Prentice Hall.
- Lees FP. Loss Prevention in Process Industries: Hazard Identification, Assessment and Control. Butterworth Heinemann.
- Bharucha E. Textbook of Environmental Studies for Undergraduate Courses. Universities Press.

<b>BPPR3109</b>	<b>Project-I</b>	<b>20 hrs</b>	<b>10 Credits</b>
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### Semester II

<b>BPL3102</b>	<b>Chemistry of Natural Products (CNP)</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### Course Learning Outcomes (CLOs):

- CLO1: To understand various chemical and spectral approaches.
- CLO2: To understand about stereoisomerism taking examples of natural products.
- CLO3: To understand pharmacology of various natural products.
- CLO4: To understand chemistry of alkaloids and glycosides.
- CLO5: To understand chemistry of medicinally important compounds.
- CLO6: To understand chemistry of various antibiotics.

Chemical and spectral approaches to characterize molecules of natural origin. Concept of stereoisomerism taking examples of natural products. Chemistry and pharmacological activity of following medicinally important terpenoids: Monoterpenes, sesquiterpenes, diterpenes and triterpenoids. Carotenoids: a- carotenoids, b- carotenes, vitamin A. Glycosides: Chemistry, pharmacological activity of digitoxin, digoxin, hecogenin, sennosides, diosgenin and sarasapogenin. Alkaloids: Chemistry, and pharmacological activity of atropine and related compounds; quinine, reserpine, morphine, papaverine, ephedrine, ergot and vinca alkaloids. Chemistry and pharmacological activity of medicinally important lignans and quassinoids, flavonoids and xanthophylls. Chemistry and therapeutic activity of penicillin, streptomycin and tetracycline.

#### Book (s) Recommended:

- Trease GE, Evans WC. Pharmacognosy. Elsevier India Pvt. Ltd.
- Aggarwal OP. Organic Chemistry Natural Products - Vol. I. Krishan Publishers.
- Aggarwal OP. Organic Chemistry Natural Products - Vol. II. Krishan Publishers.

<b>BPL3104</b>	<b>Physical Pharmaceutics-I</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### Course Learning Outcomes (CLOs):

- CLO1: To understand various properties of ideal gases.
- CLO2: To understand principles of matter and its states.
- CLO3: To understand about micromeritics and powder rheology.
- CLO4: To understand principles of viscosity and rheology in relation to drugs.
- CLO5: To understand various aspects of kinetics and drug stability.
- CLO6: To understand about buffers and their pharmaceutical applications.

Ideal Gases: Behaviour of ideal gases, Application of ideal gas law, Vapor pressure, Effect of temperature on vapor pressure, Properties of Miscible and Immiscible Liquids, Solutions. Matter and Properties of Matter: State of matter, change in the state of matter, latent heats and vapour pressure, sublimation-critical point, Eutectic mixtures, gases, aerosols - inhalers, relative humidity, liquid complexes, liquid crystals, glassy state, solids crystalline, amorphous and polymorphism. Micromeritics and Powder Rheology: Particle size and

distribution, average particle size, number and weight distribution, particle number, methods for determining particle volume, optical microscopy, sieving, sedimentation, measurement, particle shape, specific surface, methods of determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties. Viscosity and Rheology: Newtonian systems, laws of flow, cinematic viscosity, effect of temperature on flow and viscosity. Determination of viscosity, capillary, falling ball, and rotational viscometers. Non-Newtonian systems, pseudoplastic and plastic systems. Thixotropy in formulations. Rheological properties of emulsions, and theory of emulsification. Kinetics and Drug Stability: General considerations & concepts, half-life determination, Influence of temperature, light, solvent, catalytic species and other factors, Accelerated stability study, expiration dating. Buffers: Buffer equations and buffer capacity in general, buffers in the pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

**Book (s) Recommended:**

- Lachman L, Lieberman HA, Kanig JL. The Theory & Practice of Industrial Pharmacy. Varghese Publishing House.
- Sinko PJ. Martin's Physical pharmacy & Pharmaceutical sciences, B.I. Publications Pvt. Ltd.
- Subhramanyam CVS. Textbook of Physical Pharmaceutics, Vallabh Prakashan, New Delhi.
- Remington's The Science & Practice of Pharmacy Mack Publishing Co. Easton, PA.

<b>BPP3104</b>	<b>Physical Pharmaceutics-I Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: Gain knowledge about particle size distribution and particle size analysis
- CLO2: Determination of derived properties of powders like densities, porosities, compressibility etc.
- CLO3: Gain hand on experience about preparation of various types of suspensions and determination of their sedimentation parameters.
- CLO4: Understand the preparation of pharmaceutical buffers and determination of buffer capacity
- CLO5: Gain hand on experience on experiments involving tonicity adjustments.

Determination of particle size, particle size distribution and surface area using various methods of Particle size analysis. Determination of derived properties of powders like densities, porosities, compressibility, angle of repose. Study of rheological properties of various types of systems using different Viscometers. Preparation of various types of suspensions and determination of their sedimentation parameters. Preparation and stability studies of emulsions. Studies on different types of complexes and determination of their stability constants. Accelerated stability testing, shelf-life determination and expiration dating of pharmaceuticals. Preparation of pharmaceutical buffers and determination of buffer capacity. Experiments involving tonicity adjustments.

**Book (s) Recommended:**

- Carter SJ. Cooper and Gunn's Tutorial Pharmacy. CBS Publishers & Distributors.



- Remington's The Science & Practice of Pharmacy Mack Publishing Co. Easton, PA.
- Gaud RS, Gupta GD. Practical Physical Pharmacy. CBS Publishers & Distributors.
- Subhramanyam CVS. Textbook of Physical Pharmaceutics. Vallabh Prakashan.

<b>BPL3106</b>	<b>Pharmaceutical Microbiology</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### Course Learning Outcomes (CLOs):

- CLO1: To understand history of microbiology and biochemical organization of cell.
- CLO2: To understand about techniques for identification of microorganisms.
- CLO3: To understand about cultivation of microorganisms.
- CLO4: To understand about microbial genetics and gene expression.
- CLO5: To understand about various techniques of sterilization.
- CLO6: To understand about sterility testing of pharmaceutical products.
- CLO7: To understand about immunity and microbial resistance.

Introduction: Biochemical organization of the cell and transport process across cell membrane. Historical development and scope of pharmaceutical microbiology, Structure of Bacterial Cell. Identification of microbes: Stains and types of staining techniques, electron microscopy. Nutrition, cultivation and Isolation: Bacteria, Actinomycetes, Fungi and Virus. Microbial genetics and variation: Structure of gene, genetic code, transcription, translation, mutation and regulation of gene expression, bacterial enzymes. Genetic Code and Protein Synthesis: Genetic code, Components of protein synthesis, and Inhibition of protein synthesis. Brief account of genetic engineering and polymerase chain reactions. Regulation of gene expression. Control of Microbes: Physical and chemical methods: (a) Disinfectants: Dynamics of disinfection, factors affecting the process of disinfection, Evaluation of liquid disinfectants & methods of measuring growth inhibition (MIC). Types of chemical agents employed for disinfection, antisepsis and preservation with their full description & use. (b) Principles and Practice of sterilization methods: Introduction, sensitivity of microorganisms, typical survival curves for bacterial spores exposed to moist heat or gamma radiations, expression of resistance in terms of D value and Z value & sterility assurance. Sterilization methods (Heat, Gaseous, Radiations & Filtration using different filter devices) with emphasis on sterilization of items used in hospital, thermolabile drugs and injectables. Monitoring of sterilization processes. Laminar aseptic hoods and aseptic processing. Sterility Testing: Methods and media used with emphasis of the specific details of the sterility testing of parenterals and ophthalmics and other non injectable preparations such as catgut etc. Immunity: Primary and secondary, defensive mechanisms of body, microbial resistance, interferon.

#### Book (s) Recommended:

- Hugo and Russel. Pharmaceutical Microbiology. Blackwell Scientific.
- Prescott LM, Harley GP, Klein DA. Microbiology. V.C. Brown Publishers.
- Pelczar MJ, Chan ECS, Krieg NR. Microbiology. Tata McGraw Hill.
- Ananthanarayan R, Panikar CKJ. Textbook of Microbiology. Orient Longmann.
- Gupte S. The short textbook of Medical Microbiology. Jaypee Brothers.

<b>BPL3108</b>	<b>Pharmaceutical Analysis-I</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand the principles of acid base titrations.
- CLO2: To understand the principles of oxidation-reduction titrations.
- CLO3: To understand the principles of precipitation titrations.
- CLO4: To understand the principles of gravimetric analysis.
- CLO5: To understand the principles of phase solubility analysis.
- CLO6: To understand the principles of chromatography.

Acid Base Titrations: Acid base concept, role of the solvent, Relative strengths of acids and bases; Law of mass action; common-ion effect, ionic product of water, pH, Hydrolysis of salts, Handerson – Hesselbach equation; Buffer and buffer capacity: Acid base indicators, Theory of indicators, Choice of indicators; Neutralization curves (Strong acid and strong base, strong acid weak base, weak acid strong base and weak acid weak base) Polyprotic system, dissociation calculations for polyprotic acids, fractions and equilibrium concentrations of dissociating species at a given pH, salts of polyprotic acids, (Amphoteric salts and unprotonated salts), Buffer calculations for polyprotic acids, titrations of polyprotic acid, amino acid system and its titrations. Application in assay of  $\text{H}_3\text{BO}_3$ ,  $\text{HCl}$ ,  $\text{H}_3\text{PO}_4$ ,  $\text{NaOH}$  and  $\text{Na}_2\text{B}_4\text{O}_7$ . Oxidation-Reduction Titrations: Concepts of oxidation and reduction, redox reactions, equivalent weights of oxidizing and reducing agents, electrochemical cells, reduction potential, standard reduction potential, Nernst equation, cell representations, measurement of electrode potential and its application in determining the equilibrium constant of a reaction, concept of formal potential, oxidation reduction curves, redox indicators, potassium permanganate titrations, iodimetry and iodimetry, ceric sulphate titrations, potassium iodate titrations, sodium 2, 6- dichlorophenol - indophenol titrations, pharmaceutical applications. Precipitation Titrations: Precipitation reactions, solubility product, effects of common ion, acids, temperature and solvent upon the solubility of a precipitate, conditional solubility product, fractional precipitation, argentimetric titrations, ammonium or potassium thiocyanate titrations, mercuric nitrate titrations, indicators, Gay-Lussac method, Mohr's method, Volhard's method, Fajan's method, Pharmaceutical applications. Gravimetric Analysis: Precipitation techniques, the colloidal state, gravimetric factor, super saturation, co precipitation and its types, Post precipitation, digestion, washing of the precipitate, filtration, filter papers and crucibles, ignition, thermo gravimetric curves of copper sulphate, specific examples like barium as barium sulphate, aluminium as aluminium oxide, calcium as calcium oxalate and magnesium as magnesium pyrophosphate, organic precipitants. Phase Solubility Analysis: Theory, experimental procedures, applications in Pharmaceutical analysis. Chromatography: Various principles of chromatography including adsorption, partition, ion exchange, size exclusion, gel and other methods. Gas chromatography: Introduction; Principles of gas chromatography, basic GLC apparatus, carrier gases; sample introduction, column, column efficiency, solid support, liquid phases, branches of gas chromatography; Detectors, temperature effect; HPLC: Introduction and methods for qualitative and quantitative analysis using HPLC.

**Book (s) Recommended**

- Mendham J, Denney RS, Barnes JD, Thomas MJK. Vogel's Textbook of Quantitative chemical analysis. Addison Wesley Longman Ltd.



- Chatwal GR, Anand SK. Instrumental Methods of Chemical Analysis. Himalaya Publishing House.
- Kamboj PC. Pharmaceutical Analysis Volume I, II & III, Vallabh Prakashan.
- Ravi Shankar. Textbook of Pharmaceutical Analysis. RX Publisher.
- Kasture AV, Mahadik KR. Pharmaceutical Analysis, Vol-I & II. Nirali Prakashan.

<b>BPPR3110</b>	<b>Project-II</b>	<b>20 hrs</b>	<b>10 Credits</b>
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### 13. Course Syllabus: B.Sc. (Pharmaceutical Chemistry) Year II

#### Semester III

<b>BPL3211</b>	<b>Pharmaceutical Chemistry-II (Organic Chemistry)</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### Course Learning Outcomes (CLOs):

- CLO1: To understand basic facts related to structure and properties of organic compounds.
- CLO2: To gain knowledge about preparation and properties of aldehydes and ketones.
- CLO3: To gain knowledge about stereochemistry of organic compounds.
- CLO4: To understand nomenclature, preparation and reactions of alkane.
- CLO5: To gain knowledge about chemistry and analysis of proteins and peptides.
- CLO6: To gain knowledge about preparation and reactions of alcohols and ethers.

Structure and Properties: Organic chemistry, structural theory, chemical bond, quantum mechanics, atomic orbitals, electronic configuration, molecular orbitals, bond lengths, bond angles, bond energy, polarity of bonds, polarity of molecules, dipole moment, structure and physical properties including melting point, boiling point and solubility, acidity and basicity, isomerism. Aldehydes and Ketones: Nomenclature of aldehydes and ketones (carbonyl compounds), preparation of aldehydes and ketones. Reactions of aldehyde and ketones: Oxidation, reduction, addition of Grignard reagents, Cannizaro reaction. Stereochemistry of Organic Compounds: Stereoisomers, enantiomers, diastereoisomers, optical activity, chiral centre, racemic modification, meso-structures, configuration, reactions involving stereoisomers, stereoselective and stereospecific reactions. Geometric isomers, conformational isomers, configurational isomers, conformational analysis of ethane and n-butane, conformations of cyclohexanes, axial and equatorial bonds, Newman projections, Fischer and Wedge formula. Relative and absolute configuration, sequence rules, D & L, R & S and E & Z system of nomenclature. Alkanes: Nomenclature of straight and branched chain alkanes and alkyl groups, classification of carbon atoms of alkanes, isomerism, sources, methods of preparation, physical properties and chemical reactions. Mechanism of free radical halogenation of alkanes, orientation, reactivity and selectivity, chlorofluorocarbons and ozone layer. Proteins and Nucleic Acid: Structure of amino acids, amino acids as dipolar ions, isoelectric point, configuration of natural amino acids, preparation and reactions of amino acids, peptides, geometry of peptide linkage, determination of structure of peptides, terminal residue analysis, partial hydrolysis, synthesis of peptides, classification, function and

denaturation of proteins, structure of proteins, peptide chain, side chains, electrophoresis, conjugated proteins, coenzymes, secondary structure of proteins. Alcohol, Ethers and Role of the Solvent: Nomenclature, methods of preparation, physical properties and chemical reactions. Role of Solvent: Secondary bonding, solubility of non-ionic and ionic solutes, protic and aprotic solvents, ion pairs, role of solvent in substitution reactions, phase-transfer catalysis.

**Book (s) Recommended:**

- Morrison RT, Boyd RN. Organic Chemistry. Prentice-Hall of India, Pvt. Limited, New Delhi.
- Solomons G, Fryhle C, Johnson R. Organic Chemistry. Wiley (Singapore).
- Smith MB, March J. March's Advanced Organic Chemistry: Reactions, Mechanisms and Structure. Wiley.

<b>BPL3213</b>	<b>Physical Pharmaceutics-II</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand various physicochemical properties of drug molecules.
- CLO2: To understand various properties of colloidal dispersions.
- CLO3: To gain knowledge about formulation and stability suspensions and emulsions.
- CLO4: To understand mechanism of solute-solvent interactions.
- CLO5: To understand properties of ideal and real solutions.
- CLO6: To understand distribution law and its applications.

Surface and Interfacial Phenomena: Liquid interface, surface and interfacial tensions, surface free energy, measurement of surface and interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB classification, solubilization, detergency, adsorption at solid interfaces, solid- gas and solid liquid interfaces, complex films, electrical properties of interface. Dispersion Systems: (a) Colloidal Dispersions: Definition, types, properties of colloids, protective colloids, applications of colloids in pharmacy. (b) Suspensions: Interfacial properties of suspended particles, settling in suspensions, theory of sedimentation, effect of Brownian movement, sedimentation of flocculated particles, sedimentation parameters, wetting of particles, controlled flocculation, flocculation in structured vehicles, rheological considerations. (c) Emulsions-types, theories, physical stability. Solubility of drugs: (a) Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, quantitative approach to the factors influencing solubility of drugs, Dissolution & drug release, diffusion principles in biological systems. (b) Solubility of gas in liquids. (c) Solubility of liquids in liquids, (Binary solutions, ideal solutions). (d) Distribution law, its limitations and applications.

**Book (s) Recommended:**

- Sinko PJ. Martin's Physical pharmacy & Pharmaceutical sciences, B.I. Publications Pvt. Ltd.
- Subhramanyam CVS. Textbook of Physical Pharmaceutics, Vallabh Prakashan, New Delhi.
- Troy DB, Beringer P. Remington's The Science & Practice of Pharmacy. Mack Publishing Co. Easton, PA.

<b>BPL3215</b>	<b>Pharmaceutical Operation-1</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand various types of fluid flow and material handling.
- CLO2: To understand various filtration and centrifugation techniques.
- CLO3: To gain knowledge about dehumidification and humidity control.
- CLO4: To understand about refrigeration and air conditioning.
- CLO5: To gain knowledge about various types of corrosion.
- CLO6: To understand about thermometers and pumps.

Unit Operations: Introduction, basic laws. Fluid Flow: Types of flow, Reynold's number, Viscosity, Concept of boundary layer, basic equations of fluid flow, valves, flow meters, manometers and measurement of flow and pressure. Material Handling Systems: Liquid handling- Different types of pumps. Gas handling- Various types of fans, blowers and compressors. Efficiency test of Air compressor. Solid handling- Bins, Bunkers, Conveyers, Air transport. Filtration and Centrifugation: Theory of filtration, filter aids, filter media, industrial filters including filter press, rotary filter, edge filter, etc. Factors affecting filtration, mathematical problems on filtration, optimum cleaning cycle in batch filters. Principles of centrifugation, industrial centrifugal filters, and centrifugal sedimenters. Dehumidification and Humidity Control: Basic concepts and definition, wet bulb and adiabatic saturation temperatures, Psychrometric chart and measurement of humidity, application of humidity measurement in pharmacy, equipments for dehumidification operations, principles of humidity and humidity control. Refrigeration and Air Conditioning: Principles and applications of refrigeration and air conditioning HVAC system, Type of Air filters, AHU, Ventilation units, dry & wet scrubbers, dust extraction system, Filtration concepts, clean room classification as per ISO14644. Material of Construction: General study of composition, corrosion, resistance, Properties and applications of the materials of construction with special reference to stainless steel and glass. Factors affecting the choice. Temperatures and Its Measurements- Concept of Heat, Temperature and its Measurements, Liquid Thermometers and Mercury Thermometers, Bimetallic Thermometers, Platinum Resistance Thermometers, Thermoelectric Thermometers, Pyrometers, Factors for Selection of Thermometers for Particular Use, Temperature Range and Comparison of Various Thermometers. Vacuum Science and Technology- Introduction to Vacuum Technology, Physical Parameters at Low Pressure, Classification of Vacuum Ranges, General Idea of Vacuum Pump and System, Classification of Vacuum Pumps, Exhaust Pumps and their Characteristics, Measurements of Low Pressure.

**Book (s) Recommended:**

- Badger WL, Banchero JT. Introduction to Chemical Engineering. McGraw Hill, London.
- McCabe WL, Smith JC, Harriott P. Unit Operations of Chemical Engineering. McGraw Hill, London.
- Badger WL, Banchero JT. Introduction to Chemical Engineering. McGraw Hill International Book.
- Subrahmanyam CVS. Pharmaceutical Engineering: Principles and Practices. Vallabh Prakashan, New Delhi.
- Hadkar UB. Practical Physical Pharmacy & Physical Pharmaceutics. Nirali Prakashan.

<b>BPP3215</b>	<b>Pharmaceutical Operation-1 Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO 1: Gain knowledge about flow of fluids and their pressure.
- CLO 2: Evaluation of filter media, determination of filtration rate and factors affecting filtration.
- CLO 3: To demonstrate applications of centrifugation.
- CLO 4: To study about thermometers and psychometric charts.
- CLO 5: To determine humidity-use of Dry Bulb and Wet Bulb.

Measurement of flow of fluids and their pressure, determination of Reynold's number and calculation of Frictional losses. Evaluation of filter media, determination of rate of filtration and Study of factors affecting filtration. Experiments to demonstrate applications of centrifugation. Thermometers and Psychometric charts. Determination of humidity-use of Dry Bulb and Wet Bulb. Workshop practice of basic maintenance & mechanics.

**Book (s) Recommended:**

- Prager G. Practical Pharmaceutical Engineering. John Wiley & Sons.
- Hadkar UB. Practical Physical Pharmacy & Physical Pharmaceutics. Nirali Prakashan.
- Gaud RS, Gupta GD. Practical Physical Pharmacy. CBS Publishers & Distributors, New Delhi.
- Kasture PV, Paradkar AR, Parakh SR, Gokhale SB. Practical Pharmaceutics- II. Nirali Prakashan.

<b>BPL3217</b>	<b>Pharmaceutical Regulatory Affairs</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand Drugs and Cosmetics Act 1940.
- CLO2: To understand The Patents and Designs Act 1970.
- CLO3: To gain knowledge about various Drug Regulatory Agencies globally.
- CLO4: To understand about preparation of documents for New Drug Application (NDA).
- CLO5: To gain knowledge about patent filing procedure.
- CLO6: To understand about harmonization of the regulatory requirements and the quality management system.

An overview of Drugs and Cosmetics Act 1940 and rules there under, The Patents and Designs Act 1970, Trademarks. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India (CDSCO), US (FDA), EU (EMA), Japan (PMDA), UK (MHRA), Australia (TGA) & WHO. Preparation of documents for New Drug Application (NDA) as per requirements of FDA and EUDRA guidelines. GMP requirements as per CFR 210-211 and ICH Q8, Q9 and Q10. Master Files, Out of specification. Stability studies as per ICH, EUDRA, FDA, and Analytical Methodology. Patent discussion with emphases on: Patentable subject matter, Non-patentable subject matter, Criteria for getting a patent, Types of patent and its usefulness. Filing procedure for patents, patent co-operation treaty. Trade related aspects of IPR. Harmonization of regulatory requirements: Study of ICH common technical documents. Harmonization of Pharmacopoeial standards. Regulatory considerations of Pre-clinical and clinical evaluations with special

reference to legislation and guidelines of good clinical practice in US, European community and Japan. Study of Environment Act, Factory Act, Industry Act, Consumer Protection Act, Narcotic Psychotropic Substance Act and Copy Right Act. CFR: Quality Management Systems, GLP, GCP. SUPAC guideline

**Book (s) Recommended:**

- The Pharmaceutical Regulatory Process, Current edition. – Ira R. Berry, Robert P. Martin
- Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh
- FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, Current edition – Douglas J. Pisano and David S. Mantus
- Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.

<b>BPPR3219</b>	<b>Project-III</b>	<b>20 hrs</b>	<b>10 Credits</b>
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**Semester IV**

<b>BPL3212</b>	<b>Physiology and Pharmacology-I</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand about gastrointestinal and respiratory system.
- CLO2: To gain knowledge about CNS and ANS.
- CLO3: To understand urinary system and its disorders.
- CLO4: To gain knowledge about reproductive & endocrine system and sense organs.
- CLO5: To understand various food requirements.
- CLO6: To gain knowledge about various communicable diseases.

GIT system and associated endocrines; those of liver, pancreas and gall-bladder various gastrointestinal secretion and their role in the absorption and digestion of food. Disorder of digestive system. Respiratory System: Anatomy of respiratory organs, functions of respiration, mechanism and regulation of respiration, respiratory volumes and vital capacity. Central Nervous System: Functions of different parts of brain and spinal cord. Neurohumoral transmission in the central nervous system, reflex action, electroencephalogram, specialized functions of the brain, Cranial nerves and their functions. Autonomic Nervous System: Physiology and functions of the autonomic nervous system. Mechanism of neurohumoral transmission in the A.N.S. Urinary System: Various parts, structures and functions of the kidney and urinary tract. Physiology of urine formation and acid-base balance. Diseases of the urinary system. Reproductive System: Male and female reproductive systems and their hormones, physiology of menstruation, coitus and fertilization. Sex differentiation, spermatogenesis & oogenesis. Pregnancy its maintenance and parturition. Endocrine System: Basic anatomy and physiology of Pituitary, Thyroid, Parathyroid, Adrenals, Pancreas, Testes and Ovary, their hormones and functions. Sense Organs: Basic anatomy and physiology of the eye (vision), ear (hearing), taste buds, nose (smell) and skin (superficial receptors). Classification of food requirements: Balanced diet, nutritional deficiency disorders, their

treatment and prevention, specifications for drinking water. Communicable diseases: Brief outline, their causative agents, modes of transmission and prevention (Chicken pox, measles, influenza, diphtheria, whooping cough, tuberculosis, poliomyelitis, helminthiasis, malaria, filariasis, rabies, trachoma, tetanus, leprosy, syphilis, gonorrhoea, and AIDS).

**Book (s) Recommended:**

- Tortora GJ, Grabowski SR. Principles of Anatomy and Physiology. Collins College Publishers, Luciano, New York.
- Ganong WF. Review of Medical Physiology. Prentice-Hall.
- Parmar NS. Health Education and Community Pharmacy. CBS Publishers & Distributors, New Delhi.
- Guyton AC, Hall JE. Textbook of Medical Physiology. W.B. Sanders Co.

<b>BPP3212</b>	<b>Physiology and Pharmacology-I Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: Gain knowledge about different types of tissues.
- CLO2: Determination of bleeding and clotting time.
- CLO3: Gain hand on experience to estimate haemoglobin value and blood pressure.
- CLO4: Understanding of properties of drugs and the ways in which these properties react along with their mechanisms of action.
- CLO5: Understanding experiments on detection of blood groups and measurement of erythrocyte sedimentation rate.

Microscopic studies of different tissues. Simple experiments involved in the analysis of normal and abnormal urine. Collection of specimens, appearance, determination of pH of urine by pH meter. Quantitative determination of Sugars, proteins, urea, lipid profile, uric acid & creatinine. Physiological experiments on nerve-muscle preparations. Determination of vital capacity, experiments of spirometry. Estimation of SGOT, SGPT, Alkaline phosphatase and Bilirubin in the serum.

**Book (s) Recommended:**

- Tortora GJ, Grabowski SR. Principles of Anatomy and Physiology. Collins College Publishers, Luciano, New York.
- Ganong WF. Review of Medical Physiology. Prentice-Hall.
- Parmar NS. Health Education and Community Pharmacy, CBS Publishers & Distributors, New Delhi.
- Ghai CL. A Textbook of Practical Physiology. Jay Pee Brothers, New Delhi.
- Guyton AC, Hall JE. Textbook of Medical Physiology. W.B. Sanders Co.

<b>BPL3214</b>	<b>Biochemistry</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand major pathways of carbohydrates metabolism.
- CLO2: To understand major pathways and importance of lipid metabolism.
- CLO3: To gain knowledge about biological oxidation (respiratory chain).



- CLO4: To understand biosynthesis of amino acid, and urea cycle, metabolic disorder of urea cycle.
- CLO5: To gain knowledge about the metabolism of sulphur containing amino acid.
- CLO6: To understand genetic organization of mammalian genome and mechanism of enzyme action.

**Carbohydrate Metabolism:** Conversion of polysaccharide to glucose-1-phosphate, Glycolysis and fermentation and their regulation, gluconeogenesis and glycogenolysis, Metabolism of galactose and galactosemia, role of sugar nucleotides in biosynthesis, and Pentose phosphate pathway. The Citric Acid Cycle: Significance, reactions and energetic of the cycle, Amphibolic role of the cycle, and Glyoxalic acid cycle. **Lipids Metabolism:** Oxidation of fatty acids,  $\beta$ -oxidation & energetic,  $\beta$ -oxidation,  $\beta$ -oxidation, Biosynthesis of ketone bodies and their utilization, Biosynthesis of saturated and unsaturated fatty acids, Control of lipid metabolism, Essential fatty acids & eicosanoids (prostaglandins, thromboxanes and leukotrienes), phospholipids, and sphingolipids. **Biological Oxidation:** Enzymes and co-enzymes involved in oxidation reduction & its control, respiratory chain its role in energy capture and its control, Inhibitors of respiratory chain and oxidative phosphorylation, Mechanism of oxidative phosphorylation. **Metabolism of Ammonia and Nitrogen Containing Monomers:** Nitrogen balance, Biosynthesis of amino acids, Catabolism of amino acids, Conversion of amino acids to specialized products, Assimilation of ammonia, Urea cycle, metabolic disorders of urea cycle, Metabolism of sulphur containing amino acids, Porphyrin biosynthesis, formation of bile pigments, hyperbilirubinemia, Purine biosynthesis, Purine nucleotide interconversion, Pyrimidine biosynthesis and Formation of deoxyribonucleotides. **Biosynthesis of Nucleic Acids:** Brief introduction of genetic organization of the mammalian genome, alteration and rearrangements of genetic material, Biosynthesis of DNA and RNA. **Enzymes:** Nomenclature, enzyme kinetics and its mechanism of action, mechanism of inhibition, enzymes and iso-enzymes in clinical diagnosis.

#### **Book (s) Recommended:**

- Conn EE, Stump PK. Outlines of Biochemistry. John Wiley & Sons, New York.
- Nelson DL, Cox MM. Lehninger Principles of Biochemistry. Macmillan.
- Satyanarayana U, Chakrapani U. Biochemistry. Elsevier.
- Rama Rao AS. A Textbook of Biochemistry. UBS Publishers.
- Jain JL, Jain S, Jain N. Fundamentals of Biochemistry. S. Chand Publishers.

<b>BPL3216</b>	<b>Pharmaceutical Process-I</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### **Course Learning Outcomes (CLOs):**

- CLO1: To understand liquid dosage forms.
- CLO2: To gain knowledge about formulation of semi solid dosage forms.
- CLO3: To gain knowledge about formulation of pharmaceutical aerosols.
- CLO4: To understand the concept of cosmetology and its formulation methods.
- CLO5: To understand various novel drug delivery system.
- CLO6: To gain knowledge about bioavailability and bioequivalence.

**Liquid Dosages Forms:** Introduction, types of additives used in formulations, Vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubilizers, colors, flavours

and others, manufacturing packaging and evaluation of clear liquids, suspensions and emulsions official in pharmacopoeia. Semisolid Dosage Forms: Definitions, types, mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semisolids, clear gels manufacturing procedure, evaluation and packaging. Suppositories: Classification, Ideal requirements, bases, manufacturing procedure, packaging and evaluation. Pharmaceutical Aerosols: Definition, propellants, general formulation, manufacturing and packaging methods, pharmaceutical applications. Ophthalmic Preparations: Requirements, formulation, methods of preparation, containers, evaluation. Cosmeticology and Cosmetic Preparations: Fundamentals of cosmetic science. Novel Drug Delivery Systems and Controlled release (CR) delivery systems: Principle, Advantages and Disadvantages, Classification and types of oral drug delivery system, transdermal and parenteral CR drug delivery agents including Mucoadhesive, Gastroretentive, MAB based delivery systems, Nanoparticle and nanotechnology, vesicular systems including liposomes, nanosomes etc. Bioavailability of dosage forms and Bioequivalence: Evaluation methods: In vitro dissolution studies for solid oral dosage forms, Federal perspectives on Immediate Release (IR) and Extended Release (ER) products. Brief Concepts of Biopharmaceutics Classification Scheme (BCS), in-vitro in-vitro correlation and bio-waiver. Important federal considerations for bio-availability and bio-equivalence studies for oral products; Statistical considerations including Crossover ANOVA.

#### **Book (s) Recommended:**

- Lachman L, Lieberman HA, Kanig JL. The Theory & Practice of Industrial Pharmacy.
- Aulton ME. Pharmaceutics- The Science of Dosage Form Design, Churchill Livingstone, New York.
- Ansel's pharmaceutical Dosage Forms & Drug Delivery Systems.
- Lieberman HA, Lachman L, Sachwartz JB." Pharmaceutical Dosage Forms: Tablets".

<b>BPL3218</b>	<b>Industrial Pharmacy &amp; Packaging Technology</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### **Course Learning Outcomes (CLOs):**

- CLO1: To understand various building premises.
- CLO2: To understand testing of various pharmaceutical dosage forms
- CL03: To study manufacturing and packaging operations.
- CL04: To gain knowledge about pharmaceutical packaging.
- CL05: To gain knowledge about pharmaceutical machinery.
- CL06: To understand features of pharmaceutical containers and types of the corrugation methods.

Building and facilities design: Introduction, Principal Area, layout design for sterile & non sterile facility. Equipment: Introduction, Design, size, location and Construction of Equipment, Cleaning and Maintenance of Equipment, Automatic, Mechanical and Electronic Equipments. Manufacturing operations and control: Introduction, Sanitation of Manufacturing Premises, Mix-ups and Cross Contamination, Processing of Intermediates and Bulk product, Packaging Operations, I.P.Q.C., Release of Finished Product, Process Deviations, Charge-in of Components, Time Limitations on Production, Drug product Inspection, Expiration Dating, Calculation of Yields, Production Record Review. Pharmaceutical packaging: Status, Scope in pharmaceutical industry, Classification of



packaging material, Primary and secondary packaging, Functions of packaging. Sampling and quality control of packaging materials. Desirable features and a detailed study of different types of Pharmaceutical Containers and closures (Glass, Plastics and Rubber), including their merits and demerits. Packaging machinery: including strip packaging, form, fill and seal machines, liquid and solid filling machines, capping machines. Product–Package compatibility: Stability of product, package selection and development criteria. Tamper evident packaging systems: Various types and their mechanism. Flexible packaging: Types of films, Co-extruded films, foils, coating and laminates, shrink and stretch films. Corrugated and solid fibreboards and boxes: Types of corrugation methods and types of box design and Quality control.

**Book(s) Recommended:**

- Lachman, L., Lieberman, H., Kanig, J.L. The Theory and Practice of Industrial Pharmacy. Varghese Publishing House, Bombay.
- Hickey, A.J., David Ganderton, D. Pharmaceutical Process Engineering. CRC Press.
- Dean, D.A., Evans, E.R., Hall, I.H. Pharmaceutical Packaging Technology. CRC Press.
- Aulton, M.E. Pharmaceutics: The Science of Dosage Form Design. Churchill Livingstone.

<b>BPPR3220</b>	<b>Project-IV</b>	<b>20 hrs</b>	<b>10 Credits</b>
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**14. Course Syllabus: B.Sc. (Pharmaceutical Chemistry) Year III**
**Semester V**

<b>BPL3321</b>	<b>Pharmaceutical Quality Assurance</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand various types of Validation.
- CLO2: To understand about utilities validation and cleaning validation.
- CLO3: To understand about pharmaceutical quality audits.
- CLO4: To understand about quality management, complaints and recalls.
- CLO5: To understand about quality control laboratory.

Pharmaceutical Validation: Definition, scope & organization, manufacturing process model, government regulations. Validation Master Plans, URS, DQ, IQ, and OQ & PQ of facilities, Equipment's, analytical instruments, computer systems and PLC. Utilities Validation and Cleaning Validation: Pharmaceutical Water System & pure steam, HVAC system and Compressed air system validation. Equipment, working area and cleaning area validation. Process Validation: Process validation of manufacturing process of different dosage forms including sampling techniques as per guidelines of USFDA/WHO TRS. Pharmaceutical Quality Audits: Principle of Quality Audit. Quality improvement process, Quality in research and development. Quality Management: Introduction, Quality Assurance, Quality Circles, constitution, functions and benefits, Process and process management, Factors affecting process management, Problems Solving, International Standards Organization (ISO), ISO

9000, Developments of ISO 9000 Systems, ISO 9001: 2008. Complaints and Recalls: Evaluation of complaints, recall procedure, related records and documents. Quality Control Laboratory – responsibilities and laboratory practices. Routine controls on instruments, reagents, sampling plans, standard test procedures and protocols, control on animal house, data generation and storage, quality control documentation of QC facilities. Finished product release, quality review, and batch release documents.

#### **Book (s) Recommended:**

- Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan, Pune.
- GMP for Pharmaceuticals, 5th Edition, Sidney H. Willing, Marcel Decker Series
- Total Quality Management by Dale H. Bester field, Pearson Education, New Delhi.
- Total Quality Management by Dr. DD Sharma, Sultan Chand & Bros., New Delhi.
- Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials by WHO.

<b>BPL3323</b>	<b>Medicinal Chemistry-I</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### **Course Learning Outcomes (CLOs):**

- CLO1: To understand various techniques of drug design, physiochemical properties of drugs and chemistry of vitamins.
- CLO2: To understand medicinal chemistry of drugs related to adrenergic and cholinergic system.
- CLO3: To understand medicinal chemistry of antispasmodic-antiulcer, antiparkinson's and neuromuscular blocking agents.
- CLO4: To understand medicinal chemistry of antihistaminic drugs.
- CLO5: To understand chemistry, and pharmacology of analgesics and non-steroidal anti-inflammatory agents.

Physicochemical and stereo chemical aspects of drugs including bioisosterism in relation to biological activity, Types of Drug-Receptor interaction. Rationale methods of drug design (QSAR, Pharmacophore mapping, docking) Lead, Discovery of Lead, lead optimization. Vitamins: Water soluble and fat-soluble vitamins. Introduction, Structure, Stereochemistry, Nomenclature, Synthesis of specified drugs (given in parenthesis), mode of action, Structure Activity Relationships (if any) uses and Physicochemical properties of the following classes of drugs: Adrenergic and anti-adrenergic drugs including biosynthesis, storage, release and metabolism of Catecholamine (Isoprenaline, Adrenaline, Salbutamol, propranolol). Cholinergic and Anticholinesterases including biosynthesis, storage, release and metabolism of acetylcholine (Atropine, Neostigmine bromide, Pyridostigmine Bromide). Antispasmodic and Antiulcer drugs (Propantheline bromide, Dicyclomine hydrochloride). Antiparkinsonism drugs (levodopa and carbidopa). Neuromuscular blocking agents (Succinylcholine chloride, Gallamine triethiodide). Antihistamines including H<sub>1</sub> receptor antagonist Sodium Cromoglycate and Chlorpheniramine. Prostaglandins and other Eicosanoids: Nomenclature, biosynthesis and biological activity. Analgesic-antipyretics and Non-steroidal Anti-inflammatory agents: (Indomethacin and Diclofenic sodium).

**Book (s) Recommended:**

- Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. Lippincott Williams & Wilkins, Philadelphia.
- Foye's, Principles of Medicinal Chemistry. Wolters Kluwer (India), Lea & Febiger, Philadelphia.
- Hansch C. Comprehensive medicinal Chemistry Vol. IV, Quantitative Drug Design. Pergamon Press, Oxford.
- Povl Krogsgaard, Tommy, Textbook of Drug Design & Discovery, 3rd edition, 2004.
- Singh H, Kapoor VK. Medicinal and Pharmaceutical Chemistry, Vallabh Prakashan.
- Sriram D, Yogeshwari P. Medicinal Chemistry. Dorling Kindersley, Pearson Education.

<b>BPP3323</b>	<b>Medicinal Chemistry-I Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To have hands on experience of various *in silico* models for prediction of ADMET and activity.
- CLO2: To have hands on experience on synthesis and spectral analysis of some selected drugs.
- CLO3: To gain skills on establishing of pharmacopoeial standards of the drugs synthesized.
- CLO4: To gain skills in determining partition coefficient, dissociation constant and molar constant.

Exercises based on QSAR (Activity prediction of compounds by QSAR Model). Synthesis of selected drugs from the course content. Spectral analysis of the drugs synthesized. Establishing the pharmacopoeial standards of the drugs synthesized. Determination of partition coefficient, dissociation constant and molar constant.

**Book (s) Recommended:**

- Furniss BS, Hannaford AJ, Smith PWG, Tatchell AR. Vogel's Textbook of Practical Organic Chemistry. John Wiley and Sons.
- Singh HK, Kapoor VK. Practical Pharmaceutical Chemistry. Vallabh Prakashan, New Delhi.
- Mann FG, Saunders BC. Practical Organic Chemistry. Orient Longman Pvt. Ltd., Hyderabad.
- Kar A. Advanced Practical Medicinal Chemistry. New Age International, New Delhi.

<b>BPL3325</b>	<b>Pharmaceutical Process-II</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand formulation methods of Capsules.
- CLO2: To gain knowledge about microencapsulation technique and coating methods.
- CLO3: To gain knowledge about evaluation of micro capsules.
- CLO4: To gain knowledge about formulation of tablets and granulation technology.
- CLO5: To study about various preformulation factors and different routes of drug administration
- CLO6: To gain knowledge about aseptic areas.

Capsules: Introduction, types, advantages and disadvantages, material and method of preparation hard gelatin capsules, size of capsules, method of capsule filling, soft gelatin, capsule shell and capsule content, importance of base absorption and minimum/gm factors in soft capsules, evaluation, quality control, stability testing and storage of capsule dosage forms. Microencapsulation: Types of microcapsules, importance on microencapsulation in pharmacy, microencapsulation by phase separation, coacervation, multi orifice, spray drying, spray congealing, polymerization complex emulsion, air suspension technique, coating pan and other techniques, evaluation of micro capsules. Tablets: (a) Formulation of different types of tablets, granulation technology or large scale by various techniques, physics of tablets making, different types of tablet compression machinery and the equipment employed, evaluation of tablets. (b) Coating of Tablets: - Types of coating, film forming materials, formulation of coating solution, equipments for coating, coating process evaluation of coated tablets. (c) Stability kinetics and quality assurance. Parenteral Products: (a) Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment. (b) Formulation details, containers and closures and selection. (c) Prefilling treatment, washing of containers and closures, preparation of solution and suspensions, filling and closing of ampoules, vials, infusion fluids, lyophilization & preparation of sterile powders, equipment for large scale manufacture and evaluation of parenteral products. (d) Aseptic Techniques: Source of contamination and methods of prevention, design of aseptic area, laminar flow bench services and maintenance.

#### **Book (s) Recommended:**

- Aulton ME. *Pharmaceutics- The Science of Dosage Form Design*, Churchill Livingstone.
- Lachman L, Lieberman HA, Kanig JL. *The Theory & Practice of Industrial Pharmacy*, Current edition, Varghese Publishing House, Bombay.
- Banker GS, Rhode CT. *Modern Pharmaceutics*. Informa Healthcare, New York.
- Lieberman HA, Lachman L, Sachwartz JB. *Pharmaceutical Dosage Forms: Tablets*, Current edition, Marcel Dekker, N.Y.

<b>BPL3327</b>	<b>Pharmaceutical Analysis-II</b>	<b>4-0-0</b>	<b>4 Credits</b>
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#### **Course Learning Outcomes (CLOs):**

- CLO1: To gain knowledge about non-aqueous titrations.
- CLO2: To gain knowledge about various miscellaneous methods of analysis.
- CLO3: To gain knowledge about electrochemical methods of analysis.
- CLO4: To understand the concept and applications of spectrophotometry.
- CLO5: To understand various extraction methods.
- CLO6: To gain knowledge about HPLC and its applications.

Non-aqueous Titrations: Theoretical consideration, scope and limitations, acid base equilibria in nonaqueous media, titration of weak bases, titration of weak acids, indicators, and pharmaceutical products should be selected for illustration. Miscellaneous Methods of Analysis: Diazotisation titration, Kjeldahl nitrogen determination, Karl-Fischer titration, Oxygen flask combustion. Electrochemistry: The electric cell, electrode potential, half cells, types of half cells, sign convention, Nernst equation, the salt bridge, activity series, standard potential, standard hydrogen electrode, measuring the relative voltage of half cells, calculations of standard potential, reference electrodes, indicator electrodes. Potentiometry

Theoretical consideration, ion-selective electrodes, measurement of potential, location of the end point, equipment, analytical applications, direct measurement of a metal concentration, differential curves, determination of  $K_{sp}$ , pH measurements, dead-stop titrations; pH meter, pH definition, relation of pH to potential, equipment, applications. b. conductometric and High Frequency Titrations and their Applications. Polarography and Its Applications: Theory, mass transport processes, current processes, current potential relationship, polarization, choice of electrodes, effect of oxygen, instrumentation, calculation of concentration, laboratory design and safety. Spectrophotometry: Theory, Principle and Instrumentation of UV-Visible Spectrophotometry, Qualitative and Quantitative determinations using Pharmacopoeial UV based methods for single and multiple component formulations and raw materials. Theory, Principle and Instrumentation of Infrared Spectrophotometry, Qualitative determinations using Pharmacopoeial IR based methods for identification and confirmation of pharmaceutical raw materials. Theory, Principle and Instrumentation of NMR Spectrophotometry, Qualitative determinations using Pharmacopoeial NMR based methods for identification and confirmation of pharmaceutical raw materials. Theory, Principle and Instrumentation of Mass Spectrophotometry, Qualitative and Quantitative determinations using Pharmacopoeial MS based methods for identification and confirmation of pharmaceutical raw materials. LC MS: Instrumentation, working and applications. Extractions Procedures: Separation of drugs from excipients, The Craige method of multiple extraction, continuous counter - current extraction, effect of temperature, pH, inert solute, association, ion-pair formation, the emulsion problems in extractions. HPLC: HPLC-UV and HPLC-MS based analytical method development for single and multicomponent formulations.

#### **Book (s) Recommended:**

- Ravi Shankar, Textbook of Pharmaceutical Analysis, RX Publisher.
- Kamboj PC. Pharmaceutical Analysis – I, Vallabh Prakashan.
- Kamboj PC. Pharmaceutical Analysis – II, Vallabh Prakashan.
- Kamboj PC. Pharmaceutical Analysis – III, Vallabh Prakashan.
- Kasture AV, Mahadik KR. Pharmaceutical Analysis Vol-I, Nirali Prakashan.
- Kasture AV, Mahadik KR. Pharmaceutical Analysis Vol-II, Nirali Prakashan.

<b>BPP3327</b>	<b>Pharmaceutical Analysis-II Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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#### **Course Learning Outcomes (CLOs):**

- CLO1: To gain skills on preparation and standardisation of analytical reagents.
- CLO2: To gain skills on estimation of pharmacopoeial products.
- CLO3: To gain skills of miscellaneous methods of analysis.
- CLO4: To gain skills on various separation techniques.
- CLO5: To gain skills on various electrochemical methods of analysis.

Preparation and standardization of perchloric acid and sodium/ potassium/ lithium methoxides solutions; Estimations of some Pharmacopoeial products, Preparations and standardization of EDTA solution, some exercises related to Pharmacopoeial assays by complexometric titrations, Miscellaneous Determinations: Exercises involving diazotisation, Kjeldahl, Karl- Fischer, Oxygen flask combustion and gasometry methods. Determination of alcohol content in liquid galenicals, Experiments involving separation of drugs from

excipients, Chromatographic analysis of some pharmaceutical products, Exercises based on acid base titration in aqueous and non-aqueous media, oxidation reduction, Titrations using potentiometric technique, Determination of acid-base disassociation constants and plotting of titration curves using pH meter, Exercises involving polarimetry, Exercises involving conductometric and polarographic techniques.

**Book (s) Recommended:**

- Kamboj PC. Pharmaceutical Analysis – I, II and III, Vallabh Prakashan.
- Kasture AV, Mahadik KR. Pharmaceutical Analysis Vol-I & II, Nirali Prakashan.

<b>BPPR 3329</b>	<b>Project-V</b>	<b>20 hrs</b>	<b>10 Credits</b>
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**Semester VI**

<b>BPL3322</b>	<b>Dosage Form Design (DFD)</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To understand about preformulation studies.
- CLO2: To gain knowledge about applications of pro-drugs.
- CLO3: To gain knowledge about validation and stability studies.
- CLO4: To gain knowledge about performance evaluation methods.
- CLO5: To understand biopharmaceutics classification scheme and bioavailability.
- CLO6: To gain knowledge about quality by design and various optimization techniques.

Preformulation studies: Study of physical properties of drugs like physical form, particle size, shape, density, wetting, dielectric constant. Solubility, dissolution and organoleptic property and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemisation, polymerization etc., and their influence on formulation and stability of products. Study of pro-drugs in solving problems related to stability, bioavailability and elegance of formulation. Design, development and process validation methods for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions. Stabilization and stability testing protocol for various pharmaceutical products. Performance evaluation methods: In vitro dissolution studies for solid oral dosage forms, Federal perspectives on Immediate Release (IR) and Extended Release (ER) products. Brief Concepts of Biopharmaceutics Classification Scheme (BCS), Lipinski rule of five, in-vitro in-vivo correlation and bio-waiver. Important federal considerations for bio-availability and bio-equivalence studies for oral products; Statistical considerations including Crossover ANOVA. Introduction to Quality by Design and Optimization Techniques: Risk Assessment (Matrix, & FMEA), Quality Target Product Profile, Critical Quality Attributes, Critical Material Attributes, & Critical Process Parameters for various dosage forms. Concept of optimization, Optimization parameters, Design of Experiments, Statistical design, and other applications.



**Book (s) Recommended:**

- Lachman L, Lieberman HA, Kanig JL. The Theory & Practice of Industrial Pharmacy. Varghese Publishing House, Bombay.
- Banker GS, Rhode CT. Modern Pharmaceutics, 4th Ed, Informa Healthcare, New York.
- Jain NK. Controlled and novel drug delivery. CBS Publishers & Distributors, New Delhi.

<b>BPP3322</b>	<b>Dosage Form Design (DFD) Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To gain skills on various preformulation studies.
- CLO2: To gain skills related to bioavailability improvement through prodrugs.
- CLO3: To gain skills on stability studies.
- CLO4: To gain skills on dissolution testing.
- CLO5: To gain skills on bioequivalence studies.

Preformulation studies including drug-excipient compatibility studies, effect of stabilizers, preservatives etc. in dosage form design. Experiments demonstrating improvement in bioavailability through prodrug concept. Stability evaluation of various dosage forms and their expiration dating. Dissolution testing and data evaluation for oral solid dosage forms. Evaluation of Bioequivalence of some marketed products. Design, development and evaluation of controlled release formulations.

**Book (s) Recommended:**

- Bachhav V. Innovative Dosage Forms: Design and Development at Early Stage. Wiley.
- Gibson M. Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form. CRC Press.

<b>BPL3324</b>	<b>Pharmaceutical Operation-II</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To gain knowledge about stoichiometry.
- CLO2: To gain knowledge about heat transfer.
- CLO3: To gain knowledge about evaporation techniques.
- CLO4: To gain knowledge about distillation and its applications.
- CLO5: To gain knowledge about various drying methods.
- CLO6: To gain knowledge about size reduction, size separation and mixing techniques.

Stoichiometry: Unit processes material and energy balances, molecular units, mole fraction, gas laws, mole volume, primary and secondary quantities, equilibrium state, rate process, steady and unsteady states, dimensionless equations, dimensionless formulae, dimensionless groups, different types of graphic representation, mathematical problems. Heat Transfer: Source of heat, heat transfer, steam and electricity as heating media, determination of requirement of amount of steam/electrical energy, steam pressure, Boiler capacity, Mathematical problems on heat transfer, pure steam & boiler act. Evaporation: Basic concept of phase equilibrium, factor affecting evaporation, evaporators, film evaporators, single effect and multiple effect evaporators, Mathematical problems on evaporation. Distillation: Raoult's

law, phase diagrams, volatility; simple steam and flash distillations, principles of rectification, Calculation of number of theoretical plates, Azeotropic and extractive distillation. Mathematical problems on distillation. Drying: Moisture content and mechanism of drying, rate of drying and time of drying calculations; classification and types of freeze-drying dryers behaviour of solids during drying, MC, EMC, CMC and LOD dryers used in pharmaceutical industries and special drying methods. Mathematical problems on drying. Size Reduction and Size Separation: Definition, objectives of size reduction, factors affecting size reduction, laws governing energy and power requirements of mills including ball mill, hammer mill, fluid energy mill etc. Mixing: Theory of mixing, solid-solid, solid-liquid and liquid-liquid mixing equipments.

### Book (s) Recommended:

- Carter SJ. Cooper & Gunn's Tutorial Pharmacy. 6th edition, CBS Publishers & Distributors, New Delhi.
- Badger WL, Banchero JT. Introduction to Chemical Engineering. McGraw Hill International Book Co., London.
- Perry RH, Green DW. Chemical Engineers Handbook. McGraw Hill, International Editors Ltd, London.
- Subramanyam CVS, Setty JT, Suresh S, Devi VK. Pharmaceutical Engineering- Principles & Practices. Vallabh Prakashan, Delhi.

<b>BPL3326</b>	<b>Pharmaceutical Operation Management</b>	<b>4-0-0</b>	<b>4 Credits</b>
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### Course Learning Outcomes (CLOs):

- CLO1: To understand the concept management.
- CLO2: To gain knowledge about operations management.
- CLO3: To gain knowledge about quality management including TQM.
- CLO4: To understand the concept of production management.
- CLO5: To gain knowledge about JIT and lean production system.
- CLO6: To gain knowledge about purchasing management.

Concept of Management: Administrative Management (Planning, Organizing, Staffing, Directing and Controlling), Entrepreneurship development, Operative Management (personnel, Materials, Production, Financial, Marketing, Time/space, margin/ Morale), Principles of Management (Co-ordination, Communication, Motivation, Decision Making, leadership, innovation, creativity, delegation of Authority/ Responsibility, Record keeping). Operations management: concept, functions; transformation process model: inputs, process and outputs; classification of operations; responsibilities of operations manager, contribution of henryford, deming, crossby, taguchi. Process selection- project, job, batch, mass and process types of production systems. Quality Management: Introduction, Meaning, Quality Characteristics of Goods and Services, Juran's Quality Trilogy, Deming's 14 principles, Tools and Techniques for Quality Improvement, Statistical Process Control Chart, Quality Assurance, Total Quality Management (TQM) Model Concept of Six Sigma and its Application. Acceptance Sampling – Meaning, Objectives, Single Sample, Double Sample and Multiple Sample Plans with sated risk, Control charts for variables – Averages and Ranges, Control Charts for Defectives – Fraction Defective and Numbers Defective. Production Management: A brief exposure of the different aspects of Production



Management-Visible & Invisible inputs, methodology of activities, performance evaluation techniques, process flow, process know-how, maintenance management. JIT and Lean Production System: JIT Approach, Implementation requirements, Services, Kanban System. Inventory Management: Concepts, Classification, Objectives, Factors Affecting Inventory Control Policy, Inventory Costs, Basic EOQ Model, Re-order level, ABC analysis. Logistics and Franchising. Purchasing Management – Objectives, Functions, Methods, Procedure, and Value Analysis: Concepts, Stock Control Systems, Virtual Factory Concept and Production Worksheets.

**Book (s) Recommended:**

- Robbins SP, Coulter M. Management. Pearson Prentice Hall.
- Robbins SP, Judge TA. Organizational Behavior. Pearson Publication.
- Koontz H, Weihrich H. Essentials of Management. Tata McGraw Hill

<b>BPL3328</b>	<b>Medicinal Chemistry-II</b>	<b>4-0-0</b>	<b>4 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To gain knowledge about chemistry of various steroid related drugs.
- CLO2: To gain knowledge about chemistry of general and local anesthetics.
- CLO3: To gain knowledge about chemistry of sedative & hypnotics, anticonvulsants and antitussives.
- CLO4: To understand medicinal chemistry of various psychopharmacological agents.
- CLO5: To understand medicinal chemistry of various diuretics.
- CLO6: To gain knowledge about chemistry of various drugs acting on cardiovascular system.

Introduction, Structure, Stereochemistry, Nomenclature, Synthesis of specified drugs (given in parenthesis), mode of action, Structure Activity Relationships (if any) uses and Physicochemical properties of the following classes of drugs: Steroids: Biosynthesis of Cholesterol; Estrogens (Oestradiol), Nonsteroidal estrogens (Stilboesterol), Antiestrogens, Progestogens, (progesterone from stigmasterol), Synthetic Progesterone (norethisterone), antiprogestogens, oral contraceptives, androgens (biosynthesis of testosterone and its synthesis from diosgenin). General Anaesthetics: Inhalational anaesthetics, Intravenous anesthetics. Local Anaesthetics: Esters (Benzocaine), Amides (Lignocaine). Hypnotics and Sedatives: Barbiturates (Phenobarbitone); benzodiazepines (Nitrazepam). Anticonvulsants: Barbiturates; Hydantoin (Phenytoin); Oxazolidinediones (Troxidone); Benzodiazepines and Carbamazepine. Antitussive: Centrally acting Antitussive, Opium alkaloids and related agents and Synthetic Antitussives, Peripherally acting antitussives and Expectorants. Central Nervous System Stimulants: Natural and Synthetic (Nikethamide); methylxanthines (Theophyllines) and Modified methylxanthines. Psychopharmacological Agents: Antipsychotic agents: Phenothiazines (chlorpromazine); butyrophenones and miscellaneous; Antidepressants: Tricyclic antidepressants (Amitriptyline), Atypical antidepressants; Monoamine oxidase inhibitors; Anxiolytics: Meprobamate and related drugs (Meprobamate); benzodiazepines (Diazepam). Diuretics: Carbonic anhydrase inhibitors (Acetazolamide); Thiazides and related drugs (Bendrofluazide); High ceiling diuretics (Furosemide), Aldosterone antagonists (spironolactone); other potassium sparing diuretics and osmotic

diuretics. Cardiovascular agents: Cardiac glycosides; Antihypertensive agents; Antianginals and vasodilators; Antiarrhythmic drugs; Antihyperlipidemic drugs.

**Book (s) Recommended:**

- Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams & Wilkins, Philadelphia.
- Foye's, Principles of Medicinal Chemistry, Sixth Edition, Wolters Kluwer (India), Lea & Febiger, Philadelphia.
- Singh H, Kapoor VK. Medicinal and Pharmaceutical Chemistry, Vallabh Prakashan, Delhi, 2005.
- Sriram D, Yogeshwari P. Medicinal Chemistry. Dorling Kindersley, Pearson Education, New Delhi.

<b>BPP3328</b>	<b>Medicinal Chemistry-II Practical</b>	<b>0-0-4</b>	<b>2 Credits</b>
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**Course Learning Outcomes (CLOs):**

- CLO1: To gain skills about various stereo models for drugs.
- CLO2: To gain skills on synthesis of selected drugs.
- CLO3: To gain skills on spectral analysis of selected drugs.
- CLO4: To gain skills on establishing pharmacopoeial standards for drugs synthesized.

Workshop on stereo model use of some selected drugs. Synthesis of selected drugs from the course content involving two or more steps and their spectral analysis. Establishing the Pharmacopoeial standards of the drugs synthesized.

**Book (s) Recommended:**

- Furniss BS, Hannaford AJ, Smith PWG, Tatchell AR. Vogel's Textbook of Practical Organic Chemistry. John Wiley and Sons.
- Singh HK, Kapoor VK. Practical Pharmaceutical Chemistry. Vallabh Prakashan, New Delhi.
- Mann FG, Saunders BC. Practical Organic Chemistry. Orient Longman Pvt. Ltd., Hyderabad.
- Kar A. Advanced Practical Medicinal Chemistry. New Age International, New Delhi.

<b>BPPR3330</b>	<b>Project-VI</b>	<b>20 hrs</b>	<b>10 Credits</b>
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## 15. Appendix

### Calculation of SGPA & CGPA

Cumulative Grade Point Average (CGPA) calculated on a 10-point scale is used to describe the overall performance of a student. The Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA) are calculated as:

$$SGPA_i = \frac{\sum_{j=1}^n C_{ij} G_j}{\sum_{j=1}^n C_{ij}}$$

$$CGPA = \frac{\sum_{i=1}^N \left( SGPA_i * \sum_{j=1}^n C_{ij} \right)}{\sum_{i=1}^N \left( \sum_{j=1}^n C_{ij} \right)}$$

Where n = number of subjects in the Semester; N = number of Semesters;  $SGPA_i$  = SGPA for the  $i^{th}$  Semester;  $C_{ij}$  = number of credits for the  $j^{th}$  course in  $i^{th}$  Semester; and  $G_j$  = Grade point corresponding to the grade obtained in the  $j^{th}$  course.

Table below shows the grade point for every valid grade that may be awarded to a student pursuing a particular course:

Marks Range	Grade	Grade Weightage	Qualitative Meaning
80 - 100	O	10	Outstanding
70-79	A+	9	Excellent
60-69	A	8	Very Good
55-59	B+	7	Good
50-54	B	6	Above Average
45-49	C	5	Average
40-44	P	4	Pass
0-39	F	0	Fail
	AB		Absent

If the student is detained from appearing in the end term examination because of the shortage of attendance in the regular semester or is absent in the end term examination, his grade in that subject is 'AB', till he/she appears again in the end term examination and obtains a new grade.

## 16. Eligibility for the Award of Degree:

A student has to qualify/earn all course credits and to maintain a minimum CGPA of 4.5 to receive degree in B.Sc. Programs. The duration of the B.Sc. (Pharmaceutical Chemistry) program is three years - divided into 6 semesters. The maximum duration of completion of degree is 5 years.