FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **I**

Course Code: **108300101**

Course Title: **Modern Pharmaceutical Analytical Techniques**

Course Objectives: Upon completion of the course the student shall be able to

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	**UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV – Visible Spectroscopy **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectro-fluorimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	**11**
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy	**10**

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3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	**10**
4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	**10**
5	a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography**: Production of X – rays, Different X – ray diffraction methods, Bragg's law, Rotating crystal technique, X – ray powder technique, Types of crystals and applications of X – ray diffraction.	**9**
6	**Potentiometry**: Principle, thermal transitions and instrumentation (heat flux and power compensation and designs) working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis:** Polymer behaviour, factors affecting and instrumentation, and working, application of TGA	**9**

Reference Books:

1	Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2	Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3	Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4	Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5	Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6	Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7	Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Pedagogy:

1. ICT tools (LCD projector, Laptop)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
40	40	10	10	0	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Explain theory and applications of various spectroscopic techniques like UV-visible, IR, fluorimetric and atomic spectroscopy	**30**
CO-2	Explain theory and applications of various chromatographic separation techniques	**20**
CO-3	Learn theory and applications of Mass and NMR spectroscopy	**30**
CO-4	Understand basic principles and applications of electrophoresis and X-ray methods	**10**
CO-5	Learn theory and applications of thermal and potentiometric methods of analysis	**10**

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2020
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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **I**

Course Code: **108310102**

Course Title: **Advanced Pharmaceutical Analysis**

Course Objectives: Upon completion of this course the student should be able to
1. Learn appropriate analytical skills required for the analytical method development
2. Study principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems
3. Analyze impurities in drugs, residual solvents and stability studies of drugs and biological products

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	**Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines **Impurities in new drug products:** Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents	10

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2	**Elemental impurities:** Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis **Stability testing protocols:** Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations.	**10**
3	**Impurity profiling and degradent characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelf- life calculation, WHO and ICH stability testing guidelines. Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	**10**
4	**Stability testing of phyto-pharmaceuticals:** Regulatory requirements, Protocols, HPTLC/HPLC finger printing interactions and complexity.	**10**
5	**Biological tests and assays of the following:** a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Anti-venom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)	**10**
6	**Immunoassays (IA)** Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminescence IA, Quantification and applications of IA.	**10**

Reference Books:

1	Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2	Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4 th Edition, CBS publishers, New Delhi, 1997.
3	Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, JohnWiley & Sons, 1982
4	Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5	Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6	Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7	The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964
8	Indian Pharmacopoeia Vol – I, II & III 2007, 2010, 2014.
9	Methods of sampling and microbiological examination of water, first revision, BIS
10	Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons
11	Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005

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12	Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13	The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14	ICH Guidelines for impurity profiles and stability studies.

Pedagogy:

1. ICT Tools (Powerpoint presentation, video sharing on Projector)
2. Traditional teaching methodology (Blackboard)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analysing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
40	35	10	10	5	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Discuss concept and guidelines of impurities and impurity analysis	**35**
CO-2	Learn stability studies of pharmaceutical drugs	**25**
CO-3	Describe Immunoassay and bioassay of medicinal compounds	**30**
CO-4	Summarize stability testing of phytopharmaceuticals	**10**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **:I**

Course Code: **: 108310103**

Course Title: **: Pharmaceutical Validation**

Course Objectives: Upon completion of this course the student should be able to
1. Explain the aspect of validation
2. Carryout validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipments
4. Validate the manufacturing facilities

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory Equipments	12
2	Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.	12
3	Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP)	12

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4	Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance21 CFR part 11 and GAMP 5.	**12**
5	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual, Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications – provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	**12**

Reference Books:

1	. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2	The Theory& Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3	Validation master plan by Terveeks or Deeks, Davis Harwood International publishing.
4	Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5	Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6	Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Inter – pharm Press
8	Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9	Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

Pedagogy:
Power Point presentation

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analysing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
40	30	20	10	0	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Describe the concept of validation and qualification in pharmaceutical industry	**30**
CO-2	Explain the process for validating various pharmaceutical instruments and calibration of glassware	**20**
CO-3	Explain the validation of pharmaceutical utility systems and cleaning procedures	**20**
CO-4	Describe the validation of analytical methods and computerized systems	**20**
CO-5	Explain the intellectual property rights and patents with respect to pharmaceuticals	**10**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **:Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **:I**

Course Code: **:108310104**

Course Title: **:Food Analysis**

Course Objectives:
At completion of this course student shall be able to understand various analytical techniques in the determination of
1. Food constituents
2. Food additives
3. Finished food products
4. Pesticides in food
5. Student shall have the knowledge on food regulations and legislations.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	**Carbohydrates:** classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fiber, Crude fiber and application of food carbohydrates. **Proteins:** Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins	12
2	**Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. **Vitamins:** classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.	12

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3	**Food additives:** Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. **Pigments and synthetic dyes:** Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes	**12**
4	General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.	**12**
5	**Pesticide analysis:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphrus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US – FDA.	**12**

Reference Books:

1	The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2	Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3	Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4	Analysis of Food constituents – Multon, Wiley VCH.
5	Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

Pedagogy:

1. ICT Tools (Power point presentation, video sharing on Projector)
2. Traditional teaching methodology (Blackboard)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analysing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
35	30	20	10	5	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Understand physico-chemical properties of carbohydrates, lipids and proteins	**30**
CO-2	Learn quality control evaluation of fats and oils	**20**
CO-3	Analyze food additives, fermented products, milk and milk products	**20**
CO-4	Learn the effect of pest and insects on foods and determine the content of pesticides in foods	**20**
CO-5	Understand food regulations and legislations	**10**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **I**

Course Code: **108310105**

Course Title: **Pharmaceutical Analysis Practical – I**

Course Objectives:
At completion of this course student shall be able to
1. Apply analytical techniques in determination of Bulk drug, drugs in dosage form
2. Perform quantitative estimation of functional groups
3. Perform analysis of food products and additives
4. Perform calibration and validation of Instruments and process

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
-	-	12	6	-	-	50/20	100/40	150/60

* **J**: Jury; **V**: Viva; **P**: Practical

List of Practicals:

1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2	Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry
7	Assay of official compounds by different titrations
8	Assay of official compounds by instrumental techniques.
9	Quantitative determination of hydroxyl group.
10	Quantitative determination of amino group
11	Colorimetric determination of drugs by using different reagents
12	Impurity profiling of drugs
13	Calibration of glass-wares
14	Calibration of pH meter

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15	Calibration of UV-Visible spectrophotometer
16	Calibration of FTIR spectrophotometer
17	Calibration of GC instrument
18	Calibration of HPLC instrument
19	Cleaning validation of any one equipment
20	Determination of total reducing sugar
21	Determination of proteins
22	Determination of Saponification value, Iodine value, Peroxide value, Acid value in food products
23	Determination of fat content and rancidity in food products
24	Analysis of natural and synthetic colors in food
25	Determination of preservatives in food
26	Determination of pesticide residue in food products
27	Analysis of vitamin content in food products
28	Determination of density and specific gravity of foods
29	Determination of food additives

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Perform assay of pharmaceutical compounds using UV spectroscopy, chromatography and titrimetric methods	**45**
CO-2	Calibrate analytical instruments	**20**
CO-3	Carry out quality evaluation of food product and food additives	**15**
CO-4	Perform quality control evaluation of fats and oils	**20**

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: **Master of Pharmacy (Pharmaceutical Analysis)**

Semester: **I**

Course Code: **108310106**

Course Title: **Seminar/Assignment**

Course Objectives:
At completion of this course student shall be able to
1. Develop skills to collect and organize data
2. Acquire knowledge on the current topic in field Pharmaceutical science
3. Perform effective presentation and communication skill

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
-	-	8	4	-	-	100/40	-	100/40

* **J**: Jury; **V**: Viva; **P**: Practical

Guidelines

Seminar will be given on the current topic in the field of Pharmaceutical science. Student will gather information, compile data in the form of report and give presentation on the topic given.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Develop skills to collect and organize information for the given topic	25
CO-2	Compile data and develop write-up skill on the topic given for seminar presentation	25
CO-3	Develop communication and presentation skills	25
CO-4	Effectively respond to the queries and questions raised	25

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