## FACULTY OF PHARMACEUTICAL SCIENCES

## Effective from Academic Batch: 2025 – 26

**Programme** : **Master of Pharmacy (Pharmaceutical Quality Assurance)**

**Semester** : **II**

**Course Code** : **108330201**

**Course Title** : **Hazards and Safety Management**

**Course Objectives:** Upon completion of this course, it is expected that students will be able to

1. Understand about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the industry environment.
4. Ensure safety standards in pharmaceutical industry
5. Provide comprehensive knowledge on the safety management
6. Empower an idea to clear mechanism and management in different kinds of hazard management system
7. Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

**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 | - | - | 100/50 |

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

**Detailed Syllabus:**

| Sr. | Contents | Hours |
|---|---|---|
| 1 | **Multidisciplinary Nature of Environmental Studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems,<br>a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources<br>**Ecosystems:** Concept of an ecosystem and Structure and function of an ecosystem.<br>**Environmental Hazards:** Hazards based on Air, Water, Soil and Radioisotopes. | 12 |



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| | | |
|---|---|---|
| **2** | **Air Based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA)<br>**Fire Protection System:** Fire prevention, types of fire extinguishers and critical Hazard management system. | **12** |
| **3** | **Chemical Based Hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept. | **12** |
| **4** | **Fire and Explosion:** Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations,<br>**Fire protection system:** Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. | **12** |
| **5** | **Hazard and Risk Management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools<br>Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services. | **12** |

**Reference Books:**


| | |
|---|---|
| **1** | Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore |
| **2** | "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety |
| **3** | Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India |
| **4** | Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press. |


**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 the multidisciplinary nature of environmental studies, natural resources, ecosystems and associated environmental hazards. | **15** |
| **CO-2** | Describe air-based hazards, and design strategies for maintaining air circulation and fire protection systems in industrial settings. | **25** |
| **CO-3** | Explain chemical – based hazards using control measures, regulations, and threshold limit value (TLV) concepts to ensure workplace safety. | **20** |
| **CO-4** | Explain fire and explosion hazards and implement preventive and protective measures for minimizing fire and explosion risks. | **25** |
| **CO-5** | Describe risk management techniques and ICH guidelines for hazard assessment, accident prevention, effluent treatment, factory act and rules to meet industrial safety standards. | **15** |

| **Curriculum Revision:** | |
|---|---|
| Version: | 1 |
| Drafted on (Month-Year): | June 2025 |
| Last Reviewed on (Month-Year): | June 2025 |
| Next Review on (Month-Year): | June 2030 |



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## FACULTY OF PHARMACEUTICAL SCIENCES

## Effective from Academic Batch: 2025-26

**Programme** : **Master of Pharmacy (Pharmaceutical Quality Assurance)**

**Semester** : **II**

**Course Code** : **108330202**

**Course Title** : **Pharmaceutical Validation**

**Course Objectives:** Upon completion of this course the student should be able to understand

1. The concepts of calibration, qualification, and validation
2. The qualification of various equipment and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipment employed in the manufacture of pharmaceuticals
6. The concepts of IPR and filing a patent

**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 | - | - | 100/50 |

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

**Detailed Syllabus:**

| Sr. | Contents | Hours |
|---|---|---|
| 1 | **Introduction to validation**: Definition of Calibration, Qualification and Validation, Scope, frequency, and importance.<br>Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.<br>**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). | 10 |
| 2 | **Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.<br>**Qualification of analytical instruments:** UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS. | 10 |



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| | | |
|---|---|---|
| **3** | **Qualification of laboratory equipment**: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus<br>**Validation of Utility systems**: Pharmaceutical water system & pure steam, HVAC system, Compressed air, and nitrogen | **10** |
| **4** | **Process Validation**: Concept, Process, and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals, and aerosols.),<br>**Aseptic filling**: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.<br>**Analytical method validation**: General principles, Validation of analytical method as per ICH guidelines and USP | **10** |
| **5** | **Cleaning Validation**: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.<br>**Computerized system validation**: Electronic records and digital signature - 21 CFR Part 11 and GAMP | **10** |
| **6** | **General Principles of Intellectual Property**: Concepts of Intellectual Property (IP), 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.<br>Filing a patent application; 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.<br>Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. | **10** |

**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 |




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| | |
|---|---|
| **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. |
| **10** | Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare |
| **11** | Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Inter pharm Press |
| **12** | LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press |
| | |

**Pedagogy:**
Power Point presentation, Smart Board, Video display

**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 | 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.

**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 qualification of analytical instrument, and various equipment. | **30** |
| **CO-3** | Describe the process validation, analytical method validation, aseptic filling, cleaning validation and computerized system validation. | **30** |
| **CO-4** | Explain the intellectual property rights and patents with respect to pharmaceuticals. | **10** |

| **Curriculum Revision:** | |
|---|---|
| Version: | 1 |
| Drafted on (Month-Year): | June 2025 |
| Last Reviewed on (Month-Year): | June 2025 |
| Next Review on (Month-Year): | June 2030 |



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## FACULTY OF PHARMACEUTICAL SCIENCES

## Effective from Academic Batch: 2025-26

**Programme:** **Master of Pharmacy (Pharmaceutical Quality Assurance)**

**Semester:** **: II**

**Course Code:** **: 108330203**

**Course Title:** **: Audits and Regulatory Compliance**

**Course Objectives:** Upon completion of this course the student should be able

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

**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 | - | - | 100/50 |

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

**Detailed Syllabus:**

| Sr. | Contents | Hours |
|---|---|---|
| 1 | **Introduction**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies | 12 |
| 2 | **Role of quality systems and audits in pharmaceutical manufacturing environment**: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries. | 12 |
| 3 | **Auditing of vendors and production department**: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing,<br>**Dry Production:** Granulation, tableting, coating, capsules, sterile production, and packaging. | 12 |
| 4 | **Auditing of Microbiological laboratory**: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. | 12 |
| 5 | **Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection. | 12 |



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**Reference Books:**


| | |
|---|---|
| **1** | Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C. |
| **2** | Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications. |
| **3** | Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000. |
| **4** | Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005). |


**Pedagogy:**
Power Point presentation, Smart board, Traditional method

**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.

**Course Outcomes (CO):**

| Sr. | Course Outcome Statements | %weightage |
|---|---|---|
| **CO-1** | Describe the concept of audits. | **15** |
| **CO-2** | Describe role of quality system and audits in manufacturing environments of pharmaceutical industries. | **30** |
| **CO-3** | Explain the process for auditing of vendor and production department, Dry production. | **25** |
| **CO-4** | Explain the process for auditing of microbiological laboratory, auditing of quality assurance and engineering department | **30** |

| **Curriculum Revision:** | |
|---|---|
| Version: | 1 |
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## FACULTY OF PHARMACEUTICAL SCIENCES

## Effective from Academic Batch: 2025 – 26

**Programme** : **Master of Pharmacy (Pharmaceutical Quality Assurance)**

**Semester** : **II**

**Course Code** : **108330204**

**Course Title** : **Pharmaceutical Manufacturing Technology**

**Course Objectives:** Upon completion of this course the student shall

1. Understand the common practice in the pharmaceutical industry developments, plant layout and production planning
2. Be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

**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 | - | - | 100/50 |

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

**Detailed Syllabus:**

| Sr. | Contents | Hours |
|---|---|---|
| 1 | **Pharmaceutical industry developments**: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing.<br>**Plant layout**: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.<br>**Production planning:** General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control. | 12 |



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| | | |
|---|---|---|
| **2** | **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).<br>**Advanced sterile product manufacturing technology**: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.<br>**Process Automation in Pharmaceutical Industry:** With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).<br>**Lyophilization technology:** Principles, process, equipment. | **12** |
| **3** | **Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following non-sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).<br>**Advance non-sterile solid product manufacturing technology:** Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.<br>**Coating technology:** Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. | **12** |
| **4** | **Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. | **12** |
| **5** | **Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment, and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards, and regulatory requirements. | **12** |

**Reference Books:**


| | |
|---|---|
| **1** | Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial rd pharmacy, 3 ed., Varghese Publishers, Mumbai 1991. |
| **2** | Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006. |
| **3** | Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: nd tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005. |




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| | |
|---|---|
| **4** | Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York, 2005. ed., Marcel Dekker Inc, New York, 2005. |
| **5** | Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai. |
| **6** | Indian Pharmacopoeia. Controller of Publication. Delhi, 1996. |
| **7** | British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008. |
| **8** | United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003. |
| **9** | Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1 st Edition, UK. |
| **10** | Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york. |
| **11** | Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008. |


Pedagogy:
Traditional Teaching methodology (Blackboard)
ICT Tools (Power Point presentation, video sharing on Projector, Smart board)

**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 | 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.

**Course Outcomes (CO):**

| Sr. | Course Outcome Statements | %weightage |
|---|---|---|
| **CO-1** | Describe the concept of Pharmaceutical Industry development, Plant layout and production planning for pharmaceuticals. | **25** |
| **CO-2** | Explain the aseptic process technology, advanced sterile product manufacturing technology, Process automation technology, Lyophilization technology in pharmaceutical technology. | **25** |
| **CO-3** | Explain the Non sterile manufacturing process technology, Advance non-sterile solid product manufacturing technology, coating technology for pharmaceuticals. | **25** |
| **CO-4** | Explain containers and closures, Quality by design (QbD) and process analytical technology (PAT) for pharmaceutical. | **25** |

| **Curriculum Revision:** | |
|---|---|
| Version: | 1 |
| Drafted on (Month-Year): | June 2025 |
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| Next Review on (Month-Year): | June 2030 |



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## FACULTY OF PHARMACEUTICAL SCIENCES

## Effective from Academic Batch: 2025-26

**Programme** : **Master of Pharmacy (Pharmaceutical Quality Assurance)**

**Semester** : **II**

**Course Code** : **108330205**

**Course Title** : **Pharmaceutical Quality Assurance Practical – II**

**Course Objectives:** At completion of this course student shall be able to

1. To know Analytical techniques for the determination of pharmaceuticals
2. Able to perform analysis of contaminants in pharmaceuticals
3. To have a better understanding of calibration and validation of instruments and process
4. Prepare checklist and design layout for various pharmaceuticals.

**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 | 150/75 |

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

**List of Practicals:**

| | |
|---|---|
| **1** | Organic contaminants residue analysis by HPLC |
| **2** | Estimation of Metallic contaminants by Flame photometer |
| **3** | Identification of antibiotic residue by TLC |
| **4** | Estimation of Hydrogen Sulphide in Air |
| **5** | Estimation of Chlorine in Work Environment. |
| **6** | Sampling and analysis of $SO_2$ using Colorimetric method |
| **7** | Qualification of following Pharma equipment<br>a. Autoclave<br>b. Hot air oven<br>c. Powder Mixer (Dry)<br>d. Tablet Compression Machine |
| **8** | Validation of an analytical method for a drug |
| **9** | Validation of a processing area |
| **10** | Qualification of at least two analytical instruments |
| **11** | Cleaning validation of one equipment |
| **12** | Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester) |
| **13** | Check list for Bulk Pharmaceutical Chemicals Vendors |



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| | |
|---|---|
| **14** | Check list for tableting production |
| **15** | Check list for sterile production area |
| **16** | Check list for Water for injection. |
| **17** | Design of plant layout: Sterile and non-sterile |
| **18** | Case study on application of QbD |
| **19** | Case study on application of PAT |

**Course Outcomes (CO):**

| Sr. | Course Outcome Statements | % Weightage |
|---|---|---|
| **CO-1** | Determine Drug/Drugs Products using Modern Analytical Techniques | **35** |
| **CO-2** | Explain the qualification instruments/pharmaceutical test equipment, validation of process and analytical method. | **35** |
| **CO-3** | Design audit checklist for various pharmaceutical activities. | **20** |
| **CO-4** | Describe case study on application of QbD and PAT | **10** |

| **Curriculum Revision:** | |
|---|---|
| Version: | 1 |
| Drafted on (Month-Year): | June 2025 |
| Last Reviewed on (Month-Year): | Jane 2025 |
| Next Review on (Month-Year): | Jane 2030 |



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## FACULTY OF PHARMACEUTICAL SCIENCES

## Effective from Academic Batch: 2025-26

**Programme:** **Master of Pharmacy (Pharmaceutical Quality Assurance)**

**Semester:** **II**

**Course Code:** **108330206**

**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 | - | 100/50 |

* **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 |

| Curriculum Revision: | |
|---|---|
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