

**GANPAT UNIVERSITY****FACULTY OF PHARMACY****TEACHING AND EXAMINATION SCHEME**

Program	Master of Pharmacy (M.Pharm)	Branch	Quality Assurance	Semester	II	Version	2.0.0.0		
Effective from	2018-19	Effective for batches admitted onwards	2018-19						
S. N	Subject Code	Subject Name	Theory / Practical/ Seminar	Teaching Scheme		Examination Scheme			
				Credit	Hours Per Week	Marks			Total Marks
CE	SE	ES							
1	MQA201T	Hazards and Safety Management	Theory	4	4	10	15	75	100
2	MQA202T	Pharmaceutical Validation	Theory	4	4	10	15	75	100
3	MQA203T	Audits and Regulatory Compliance	Theory	4	4	10	15	75	100
4	MQA204T	Pharmaceutical Manufacturing Technology	Theory	4	4	10	15	75	100
5	MQA205P	Quality Assurance Practical-II	Practical	6	12	20	30	100	150
6	MEL206S	Seminar	Seminar	4	8	-	-	100	100
			Total	26	36	60	90	500	650

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Semester	II			Version	2.0.0.0				
Effective from Academic Year	2018-19			Effective for the batches Admitted onwards				June 2018	
Subject code	MQA201T		Subject Name	Hazards and Safety Management					
Teaching scheme		Examination scheme							
Credit	4			CE	SE	ES	Total	SE	ES
Hours	4		Marks	10	15	75	100	Duration	1 hr. 3 hr.
<b>Pre-requisites</b>									
Nil									
<b>Scope and Objectives:</b>									
This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provide the principle based approach to solve the complex tribulations.									
<b>Learning Outcome:</b>									
Knowledge of the various energy resources and ecosystems									
Understand air and chemical based hazards and its regulation									
Application of fire protection systems in pharmaceutical industry									
Analyze and identify different hazards in work place and selecte best practice for its prevention and control									
Evaluation of critical hazard and risk management systems in industry									
Create skills to identify, minimize or eliminate different work place hazards									
<b>Syllabus- Theory</b>									
Unit	Content								Hrs
1	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b)Water resources; c) Mineral resources; d) Energy resources e)Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes								12
2	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) 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, 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 & Tools Factory act & 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
<b>References</b>									
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 Publishing Pvt. Ltd., Ahmedabad– 380 013,India,								
4	Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press								

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Subject code	MQA202T	Subject Name	Pharmaceutical Validation						
Teaching scheme		Examination scheme							
Credit	4		CE	SE	ES	Total		SE	ES
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.
<b>Pre-requisites</b>									
Nil									
<b>Scope and Objectives:</b>									
	The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.								
<b>Learning Outcome:</b>									
	Knowledge about the various concepts of calibration, qualification, validation and intellectual property rights.								
	Understand the importance of validation and how it can be applied to industry to improve the quality of product								
	Application of knowledge in qualification of various equipments and instruments as well as process validation of different dosage forms								
	Analysis of pharmaceutical substance, drugs, instruments and computer system								
	Evaluate the data obtained from the validation, calibration and qualification								
	Create skill to perform the validation of analytical method for estimation of drugs and cleaning validation of equipments employed in the manufacture of pharmaceuticals								
<b>Syllabus- Theory</b>									
Unit	Content								Hrs
1	Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. 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. 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. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS								10
3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen								10
4	Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation-A life cycle approach. 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. Computerized system validation: Electronic records and digital signature- 21CFR 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								10

	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	
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#### References

1	B. T.Loftus &R. A.Nash, "Pharmaceutical Process Validation",Drugs and Pharm Sci. Series, Vol. 129,3rdEd.,MarcelDekkerInc.,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, 2ndEdition, by Carleton &Agalloco
5	Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.
6	Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.Cloud, Interpharm Press
8	Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton(Ed.)and James Agalloco(Ed.),Marcel Dekker
9	Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,Y.C.Lee,Yue .Zhang, Wileyl nterscience
10	Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11	Wingate G. Validating Corporate Computer Systems: Good ITPractice for Pharmaceutical Manufacturers. Interpharm Press
12	LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

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Semester	II			Version	2.0.0.0				
Effective from Academic Year	2018-19			Effective for the batches Admitted onwards				June 2018	
Subject code	MQA203T		Subject Name	Audits and Regulatory Compliance					
Teaching scheme			Examination scheme						
Credit	4			CE	SE	ES	Total	SE	ES
Hours	4		Marks	10	15	75	100	Duration	1 hr. 3 hr.
<b>Pre-requisites</b>									
Nil									
<b>Scope and Objectives:</b>									
This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.									
<b>Learning Outcome:</b>									
Knowledge about audit objectives, types, procedures and its management.									
Understand the role of quality systems and audits in pharmaceutical manufacturing environment.									
Apply a audit checklist for auditing pharmaceutical industries.									
Create audit plan and perform audit of above mentioned department in pharmaceutical industries by themselves.									
Evaluate and summarize the content of audit report and post audit activity with corrective and preventive action.									
Create audit plan and perform audit of above mentioned department in pharmaceutical industries by themselves.									
<b>Syllabus- Theory</b>									
Unit	Content								Hrs
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, 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 systems, ETP								12
<b>References</b>									
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-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).								

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Semester	II			Version	2.0.0.0				
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018	
Subject code	MQA204T		Subject Name	Pharmaceutical Manufacturing Technology					
Teaching scheme		Examination scheme							
Credit	4			CE	SE	ES	Total	SE	ES
Hours	4		Marks	10	15	75	100	Duration	1 hr. 3 hr.
<b>Pre-requisites</b>									
Nil									
<b>Scope and Objectives:</b>									
This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.									
<b>Learning Outcome:</b>									
Knowledge of various processes, their applications and problem encounter during non-sterile manufacturing.									
Understand the common practice in the pharmaceutical industry development plant layout and production planning.									
Apply the knowledge of principles and practices of aseptic technology in industry.									
Analyze parameters of Process Analytical Technology (PAT).									
Evaluate stability aspects of packaging material.									
Develop skill to apply and implement Quality by design (QbD) technique in pharmaceutical manufacturing.									
<b>Syllabus- Theory</b>									
Unit	Content								Hrs
1	Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.								12
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). 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. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenteral & Large Volume Parenteral (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). 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). 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 equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. 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,								12

	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	
<b>References</b>		
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 dosageforms: nd tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005	
4	Banker GS, Rhodes CT. Modern Pharmaceutics, 4 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 Pharmacopoeial Convention, Inc, USA, 2003.	
9	Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK	
10	Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Healthcare USA Inc. New York	
11	Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008	

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Semester	II			Version	2.0.0.0					
Effective from Academic Year	2018-19			Effective for the batches Admitted onwards				June 2018		
Subject code	MQA205P		Subject Name	Quality Assurance Practical - II						
Teaching scheme		Examination scheme								
Credit	6			CE	SE	ES	Total		SE	ES
Hours	12		Marks	20	30	100	150	Duration	1 hr.	3 hr.
<b>Learning Outcome</b>										
	Knowledge of how to perform validation of analytical methods for drugs									
	Understanding of preparation of plan layout for sterile and non-sterile processes.									
	Applications of QbD and PAT in pharma process.									
	Analyse metallic contaminants and residues by different analytical techniques.									
	Evaluate qualification protocol for various pharma process and testing equipments.									
	Prepare check list for various processes or substances.									
<b>List of Practicals</b>										
	<ol style="list-style-type: none"> <li>1. Organic contaminants residue analysis by HPLC</li> <li>2. Estimation of Metallic contaminants by Flame photometer</li> <li>3. identification of antibiotic residue by TLC</li> <li>4. Estimation of Hydrogen Sulphide in Air</li> <li>5. Estimation of Chlorine in Work Environment</li> <li>6. Sampling and analysis of SO<sub>2</sub> using Colorimetric method</li> <li>7. Qualification of following Pharma equipment <ol style="list-style-type: none"> <li>a. Autoclave</li> <li>b. Hot air oven</li> <li>c. Powder Mixer (Dry)</li> <li>d. Tablet Compression Machine</li> </ol> </li> <li>8. Validation of an analytical method for a drug</li> <li>9. Validation of analytical method for different parameters like linearity, LOD, LOQ, recovery, precision for various drugs</li> <li>10. Validation of a processing area</li> <li>11. Qualification of at least two analytical instruments</li> <li>12. Cleaning validation of one equipment</li> <li>13. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)</li> <li>14. Check list for Bulk Pharmaceutical Chemicals vendors</li> <li>15. Check list for tableting production</li> <li>16. Check list for sterile production area</li> <li>17. Check list for Water for injection</li> <li>18. Design of plant layout: Sterile and non-sterile</li> <li>19. Case study on application of QbD</li> <li>20. Case study on application of PAT</li> </ol>									



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Effective from Academic Year	2018-19	Effective for the batches Admitted onwards					June 2018		
Subject code	MEL206S	Subject Name	Seminar						
Teaching scheme	Examination scheme								
Credit	4	CE	SE	ES	Total		SE	ES	
Hours	8	Marks	-	-	100	100	Duration	-	3 hr.
<b>Pre-requisites</b>									
Nil									
<b>Scope and Objectives:</b>									
	<ul style="list-style-type: none"> <li>To develop know how of the latest development in the area of pharmaceutical science.</li> <li>To develop the presentation skill for the information collected and compiled in the form of seminar.</li> </ul>								
<b>Learning Outcome:</b>									
	Knowledge of the latest development in the area of pharmaceutical sciences								
	Understand the use of the library and internet resources for the referencing and literature purpose								
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way								
	Analyse the problems and strengthen ability for presentations and defending the viva voce								
	Evaluate the hypothesis, study design, method and results in a systemic manner								
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion								