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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Program	Master of Pharmacy		Branch/Spec.	Quality Assurance						
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.	

Pre-requisites

Nil

Scope and Objectives:

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.

Learning Outcome:

Student shall be able to understand about environmental problems among learners and Impart basic knowledge about the environment and its allied problems.

Student shall be able to develop an attitude of concern for the industry environment, ensure safety standards in pharmaceutical industry, provide comprehensive knowledge on the safety management

Student shall be able to empower an ideas to clear mechanism and management in different kinds of hazard managements system and teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Syllabus- Theory

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

References

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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Program	Master of Pharmacy			Branch/Spec.	Quality Assurance					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
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.	

Pre-requisites

Nil

Scope and Objectives:

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.

Learning Outcome:

- Student shall be able to learn the concepts of calibration, qualification and validation
- Student shall be able to understand the qualification of various equipments and instruments as well as process validation of different dosage forms
- Student shall be able to understand the validation of analytical method for estimation of drugs and cleaning validation of equipments employed in the manufacture of pharmaceuticals.

Syllabus- Theory

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 andaerosols), 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 Part11and 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. 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	10

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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Program	Master of Pharmacy		Branch/Spec.	Quality Assurance						
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.	

Pre-requisites

Nil

Scope and Objectives:

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.

Learning Outcome:

- Student shall be able to understand the importance of auditing and methodology of auditing
- Student shall be able to carry out the audit process
- Student shall learn to prepare the auditing report and check list for auditing

Syllabus- Theory

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

References

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,StephenP. Denyar.CRC Press.2000
4	Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor andFrancis (2005).

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Program	Master of Pharmacy		Branch/Spec.	Quality Assurance						
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.	

Pre-requisites

Nil

Scope and Objectives:

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Learning Outcome:

- Student shall be able to understand the common practice in the pharmaceutical industry developments, plant layout and production planning
- Student shall be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology
- Student shall have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Syllabus- Theory

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, 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	12

	regulatory requirements	
References		
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.PublicationsPvt. Ltd,Noida,2006	
3	Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosageforms: nd tabletsVol.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 ofPublication.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,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 andSons,NewJersey,2008	

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Program	Master of Pharmacy			Branch/Spec.	Quality Assurance					
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.	

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

a. Autoclave
b. Hot air oven
c. Powder Mixer (Dry)
d. Tablet Compression Machine

8. Validation of an analytical method for a drug
9. Validation of analytical method for different parameters like linearity, LOD, LOQ, recovery, precision for various drugs
10. Validation of a processing area
11. Qualification of at least two analytical instruments
12. Cleaning validation of one equipment
13. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
14. Check list for Bulk Pharmaceutical Chemicals vendors
15. Check list for tableting production
16. Check list for sterile production area
17. Check list for Water for injection
18. Design of plant layout: Sterile and non-sterile
19. Case study on application of QbD
20. Case study on application of PAT