Raffles University, Neemrana, Alwar, Rajasthan- 301705

Course: PHARMACEUTICAL QUALITY ASSURANCE	**Number of Prescribed Hours: 60**
Academic Year: 2023-24 **Programme: B.Pharmacy**	
Name of Faculty: Ms Deepika Yadav	**Year/Semester: III Year VI Sem**

SCHOOL: (SOP) School Of Pharmacy		**ACADEMIC SESSION: 2023-24**		**FOR STUDENTS' BATCH:**	
1	**Course No.**	**BP606T**			
2	**Course Name**	**PHARMACEUTICAL QUALITY ASSURANCE**			
3	**Credits**	**4 (3 Lectures+1Tutorial)**			
4	**Learning Hours**	**Theory hours**	**45**		
		Tutorial	**15**		
		Total hours	**65**		
5	**Course Objective**	1. understand the cGMP aspects in a pharmaceutical industry 2. appreciate the importance of documentation 3. understand the scope of quality certifications applicable to pharmaceutical industries 4. understand the responsibilities of QA & QC departments			
6	**Course Outcomes**	1. Knowledge on role of CGMP in Pharmaceutical industry and it's importance 2. Attain the Knowledge on Documentation in Pharmaceutical industry 3. Understand role and responsibilities of the QA & QC departments 4. Attain the Knowledge in Quality certifications Applicable in Pharmaceutical industry			
7	**Outline syllabus:**				

7.01	**Paper Code**	**Unit**	**Introduction**	**Lectures hours**	**Book tile**	**Page No**
7.02	**BP606T**	**Unit-I Quality Assurance and Quality Management concepts, Total Quality Management (TQM)**	**Quality Assurance and Quality Management concepts**: Definition and concept of Quality control, Quality assurance and GMP **Total Quality Management (TQM):** Definition, elements, philosophies **ICH Guidelines**: purpose, participants, process of harmonization, Brief overview of QSEM,with special emphasis on Q-series guidelines, ICH stability testing guidelines **Quality by design (QbD):** Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000:** Overview, Benefits, Elements, steps for registration **NABL accreditation**: Principles and procedures	12	Text book of organic chemistry by Bhal and Arun bhal	150-179
		Unit-II Organization and personnel, Equipments	**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental	16	Text book of organic chemistry by Bhal and	199-233

		and raw materials:	control, utilities and maintenance of sterile areas, control of contamination. **Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.		Arun bhal	
		Unit-III Quality Control, Good Laboratory Practices	**Quality Control:** Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	15	Text book of organic chemistry by Bhal and Arun bhal	293-318
7.03		**Unit-IV Complaints, Document maintenance in pharmaceutical industry**	**Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.	15	Text book of organic chemistry by Bhal and Arun bhal	410-447
		Unit-V Calibration and Validation, Warehousing	**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management	12	Text book of organic chemistry by Bhal and Arun bhal	448-473 & 575-597
8	**Course Evaluation**					
8.1	**Continuous Mode 10M (25%)**					
8.11	**Attendance**	4M (10%)				
8.12	Quiz, assignment open book test, field work, group discussion and seminar	6 Assignments and 3M (7.5%)				
8.13	Student – Teacher interaction	3M (7.5%)				
8.3	**End-term examination: 75%**					

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9	**Text Books & References**		
9.1	**Text books**	1. Quality Assurance Guide by organization of Pharmaceutical Products of India. 2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69. 3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications. 4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh 5. How to Practice GMP's – P P Sharma.	
9.2	**References**	6. ISO 9000 and Total Quality Management – Sadhank G Ghosh 7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms 8. Good laboratory Practices – Marcel Deckker Series 9. ICH guidelines, ISO 9000 and 14000 guidelines	
9.3	**Video References**	https://www.youtube.com/watch?v=G1HXS8r4vxA https://www.youtube.com/watch?v=0hzqHwu1i_I https://ispe.org/training/online-learning/gmp-fundamentals-organization-personnel https://www.youtube.com/watch?v=u1vb1HS8PHE https://www.youtube.com/watch?v=G6s30W937Cg	

Course Outcome Mapping with Programme Outcomes

CO's/PO's	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	M	M	S		L	M	M	L		M	S
CO2	M	M	S	S	L	M	M	L		M	S
CO3	M	M	S	S	L	M	M	L		M	S
CO4	M	M	S	S	L	M	M	L		M	S
CO5	M	M	S	S	L	M	M	L		M	S

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QUESTION BANK

LONG ESSAYS **2×10=20 Marks**

What is QSEM and discuss in details Q-series guidelines

Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing unit

Discuss the objectives and scope of GLP in Pharmaceutical industry

Discuss in detail the principles of TQM

Explain the facility requirements for maintenance of sterile manufacturing area

Discuss the importance of Good Laboratory Practices Explain briefly the protocol content of non-clinical laboratory study

List and explain Q series guidelines of ICH

Describe the requirements s of organization and personal responsibilities as per schedule M

Explain in detail the quality control test for packaging materials.

Explain ICH Q1 guidelines for stability testing of drug and drug product

Discuss briefly cGMP guidelines for construction, maintenance and sanitation of pharmaceutical unit

Explain the objectives and scope of GLP

Discuss the important principles of Total Quality Management

Describe the requirements for environmental control and layout of sterile manufacturing area

Explain the objectives and scope of GLP

Describe in-detail the features of ISO 9000 and ISO 14000.

Discuss the regulatory requirements for design, construction and plant layout of pharmaceutical manufacturing facility

Explain the quality control tests for containers used in pharmaceutical packaging

Discuss in detail about the concepts of Quality Assurance and GMP

Explain about the quality control tests for containers and rubber closures

Describe the design, construction and plant layout of a production unit

Explain scope and objectives of GLP.

Write in detail about personnel responsibilities, training and hygiene in pharmaceutical industry.

Write in detail about NABL accreditation, principles and procedures.

Give a detail account on stability testing of dosage form as per the ICH guidelines

Discuss in-detail the salient features of Schedule-M

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Explain the objectives and scope of GLP

What is QSEM and discuss in details Q-series guidelines

Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing

Discuss the important principles of Total Quality Management

SHORT ESSAYS **7×5=35 Marks**

Describe the procedure for NABL accreditation

Explain the steps involved in ISO 9000 registration

What is CTD and explain module -2

Write the significance of personnel hygiene in pharmaceutical industry

Describe the equipment selection and purchase procedure

Explain the protocol for conduct of non-clinical laboratory study

Explain the quality control tests for containers and rubber closures

Discuss the handling of return goods

Explain the importance and scope of validation

Explain the concept of QA and QC

Enlist ICH Q-series guidelines and explain any one in detail

Describe the criteria for equipment selection in pharmaceutical industry

How is cross contamination is prevented in dispensing unit

Write the reasons for disqualification of testing facilities

Describe the procedure for handling of return goods

Write a short note on quality audit and quality review

Explain the procedure for qualification of pH meter

Describe the principle of analytical method validation

Explain the principles are of TQM

Explain the scope and features of NABL accreditation

Discuss the steps involved in the purchase specification.

Write a note on maintenance of stores for raw materials

Give reasons for disqualification of testing facilities in GLP

Explain briefly the protocol for conducting Non-clinical lab studies

What are complaints and how they are evaluated?

How do you handle disposal of waste products in pharmaceutical unit.

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Write the procedurefor qualification of UV- Visible spectrophotometer

Write the elements of ISO 9000

Write the procedure for NABL accreditation

How is the cross contamination prevented in dispensing and production areas.

How do you audit vendor for ensuring purchase specification

Explain the QC test for secondary packaging material

Discuss the procedure for conducting non clinical laboratory studies.

Discuss the SOP for disposal of waste in pharmaceutical unit.

Elaborate on master formula record

Write the procedurefor qualification of UV- Visible spectrophotometer

Write a note on ISO 9000 and ISO 14000

Explain briefly about ICH stability testing

Discuss the maintenance of raw material stores

Describe the SOP for purchase specification

Explain the procedure for qualification of UV visible spectrophotometer

Write a note on material Management

Discuss the QC tests for secondary packing materials

Explain briefly CTD and its modules

Explain the handling of market complaints

Explain the elements of QbD

Describe the methods to prevent product contamination in sterile manufacturing unit

Write the minimum criteria for selection of pharmaceutical equipments

Explain the procedure for NABL accreditation

Discuss the SOP for Handling of return goods

Explain the guidelines to be followed for waste disposal in pharmaceutical industry

Write in brief the material management in industry

Describe the protocol for conduct of non-clinical laboratory study

Enlist the reasons for disqualification of testing facility

Discuss the tools and elements of QbD program

Explain the protocol for conduct of non- clinical laboratory study

Write a note on NABL Accreditation

Describe briefly regarding equipment selection and purchase specification

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Write briefly about Master Formula Record

Describe the maintenance of sterile area facilities

Write a note on Good ware house practices

What is DMF and explain its contents

Summarize the reasons for disqualification of testing facility

Write in brief on processing of pharmaceutical complaints.

Explain the elements of TQM

What are the steps involved in validation?

Differentiate between GLP and GDP.

Describe the quality control tests for containers.

Write in brief about preparation of new SOP.

Write brief note on QbD tools.

Write the process for maintenance of stores for raw materials

Write the importance of personal hygiene in pharmaceutical industry?

What criteria do you consider in location, design and construction of a sterile product

Describe the quality control tests for rubber closures

Explain the elements of QbD

Enlist Q-series of ICH guidelines

Discuss the SOP for purchase specification

Define validation? Mention types and explain each of them

Discuss the importance of BFR and MFR

Explain the protocol for conduct of non-clinical laboratory study

Describe the method of waste disposal in production department

Describe the sterile area facility maintenance requirements

Explain the steps involved in ISO 9000 registration

Write the significance of personnel hygiene in pharmaceutical industry

Describe the equipment selection and purchase procedure

Discuss the environmental control and layout of sterile manufacturing area

Differentiate the quality assurance and quality control departments in pharmaceutical industry

Explain the quality control tests for containers and rubber closures

Discuss the handling of return of goods

Explain the importance and scope of validation