Module name: Professional electives

Module Number in which the course exists: 18

Course title: Pharmaceutical Quality Control and Quality Assurance

Course code: Phar 4185

Course EtCTS: 5

EtCTS credits: 5 (This course needs a total of 5 x 27 = 135 working hours to spend in each teaching and learning as well as assessment activities). The distribution of these hours will be as follows

- Lectures = 48 hours
- Assignment (group and individual) = 10 hours
- Practical/laboratory sessions = 16 hours
- Home based study = 31 hours
- Group discussion and presentation = 10 hours
- Tutorial = 10 hours

Pre-requisite: Pharmaceutical Analysis I & II

Course description:

The course deals with different quality aspects of pharmaceutical products starting from their production to consumption by the customers. The course mainly covers areas of GMP and different quality control measures taken after the drug is released to market.

Course objectives:

At the end of the course, the student will be able to:

- ✓ Describe the concepts and philosophies of TQM & GMP
- ✓ Explain the different manufactures and controls taken on dosage forms
- ✓ Describe good laboratory practice and standard operating procedures
- ✓ Describe the major concepts of packaging and labeling of pharmaceuticals

Schedule of chapters/topics/subtopics, allotted time and reference materials for each topic

Day	Chapters and Topics/Subtopics	Time Allotted (hrs)	References
One	**Chapter One: Concepts and Philosophy of TQM, GMP (orange guide) and ISO-9000**	10	
Two	**Chapter Two: Organization and Personnel Responsibilities, Training, Hygiene**	7	
Three	**Chapter Three: Premises**	7	
	Location, Design, Plan Layout, Construction, Maintenance and Sanitations.	3	
	Environmental control, Sterile areas, control of contamination	4	
Four	**Chapter Four: Equipments**	7	
	Selection, purchase specifications, maintenance, sterilization of an area (TP & STP)	6	
	Selection, purchase specifications, maintenance, sterilization of an area (TP & STP)	1	
Five	**Chapter Five: Raw Materials**	7	
	Purchase specifications, Maintenance of stores, selection of vendors, Controls on Raw materials	7	
Six	**Chapter Six: Manufacture and Controls on Dosage Forms**	10	
	Manufacturing Documents, Master Formula, Batch Formula	2	
	Records, Standard operating procedure, Quality audits of manufacturing processes and facilities	8	
Seven	**Chapter Seven: Standard Operating Procedures**	7	
	Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilisation, membrane filtration	2	
	Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilisation, membrane filtration	5	

Eight	**Chapter Eight: Packaging and Labeling Controls**	18	
	Line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass.	5	
	Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs;	5	
	Different types of closures and closure liners; film wrapper; Blister packs, Bubble packs, shrink handling; foil/ plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes;	5	
	Quality control of packaging material & filling equipment	3	
Nine	**Chapter Nine**: **Quality Control Laboratory**	13	
	Responsibilities, Good Laboratory Practices, Routine controls, Instruments, Protocols, Non-clinical testing	7	
	Controls on animal house, Application of Computers in Quality control laboratory.	6	
Ten	**Chapter Ten**: **Finished Product Release**	7	
	Quality review, Quality audits, Batch release document	4	
	Quality review, Quality audits, Batch release document	3	
Eleven	**Chapter Eleven**: **Warehousing**	5	
	Good warehousing practice, Materials, Managements.	5	
Twelve	**Chapter Twelve:** **Waste disposal, Scrap Disposal Procedure and Records**	5 2	
	Waste disposal, Scrap disposal procedure and records	3	
Thirteen	**Chapter Thirteen: Regulatory Aspects of Pharmaceuticals & Bulk Drug Manufacturing**	7	
	Regulatory drug analysis	7	
Fourteen	**Chapter Fourteen**: **WHO Certification, Globalisation of Drug Industry, Introduction to Export of Drugs and Import Policy**	7	
Fifteen	**Final examination**		

Delivery mode/methodology:

- ✓ Active learning methods (brainstorming, group discussions, etc),
- ✓ Lecture,
- ✓ Group and individual presentation,
- ✓ Assignment
- ✓ Laboratory practice

Assessment mechanisms:

Continuous assessment & summative assessment

- Quiz (10%)
- Tests (10%)
- Assignments (15%)
- Presentation (10%)
- Lab reports and exam (20%)
- Final Exam (35%)

References:

1. Quality Assurance Guide by Organisation of Pharmaceutical products of Ethiopia.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg, Vol. 69, Decker Series
3. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications
4. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
5. How to practice GMPs – P. P. Sharma
6. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
7. The International Pharmacopoeia Vol. 1,2,3,4 - 3rd Edition, General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms