Paramedical program	
Specialization	**Pharmacy**
Course number	**020805251**
Course title	**Pharmaceutical quality control**
Credit hours	**2**
Theoretical hours	**1**
Practical hours	**3**

Brief Course Description:

To study drug, stability, analysis, packaging, and labeling. Also the course deal with bases of good manufacturing practice.

Course Objectives:
Upon the completion of the course, the student will be able to:

1. Explain the principle of drug stability
2. Distinguish the factors affecting drug stability.
3. Discuss Good storage practice,
4. Describe major types of drug analysis.
5. Discuss the types of drug packaging, and labeling.
6. Recognize principles of good manufacturing practice.

Detailed Course Description:

Unit number	Unit name	Unit content	Time needed
1.	**Drug stability and storage**	▪ **Introduction** ▪ **Factors Influencing Stability of Drugs and Drug Products** o Environmental factors affecting degradation (temp. humidity, light, microbial, O_2, CO_2 ...) o Other factors (solvent, PH, additives, chemical structure and containers, ...) ▪ **Physical degradation and its indications:** (Aging, Adsorption, Vaporization...) ▪ **Chemical degradation and its indications:** (oxidation , Hydrolysis, racemization ,dehydration isomerization ▪ **Microbial deterioration and its indications** (preservatives, prevent contamination) ▪ **Factors Affecting Rates of Degradation:** (buffers, antioxidants, Chelating agent, temperature,etc....) ▪ **Good storage conditions and drug changes during storage** ▪ **Accelerated stability study** o Prediction of shelf –life from accelerated stability study o Expiry Date o Differences Between Shelf Life and Expiration Date of a product o Batch, Lot number	

2.	**Drug analysis:**	▪ **Introduction** (purpose, monograph,….. ▪ **Physical Analysis** ▪ **Chemical Analysis:** ▪ **Chemical tests:** o Acid-base titration o Titration by precipitation. o Complex titration o Oxidation-reduction titration. ▪ **Instrumental Analysis:** o Spectral methods of analysis: (UV – visible spectrophotometer, IR spectrophotometer, NMR Spectrometry, Atomic absorption Spectroscopy and Spectrofluorometry.) o Chromatographic methods of analysis: (Paper Chromatography, Thin layer chromatography, Column chromatography, Gas chromatography ,HPLC , HPTLC and Electrophoresis, Mass spectroscopy)	
3.	**Packaging and Labeling**	▪ **Packaging:** o Definition &function o Importance of packaging o Factors determining type of packaging (unit dose containers , multi dose containers) o Types of closures (roll on closures, lug cap, crown caps,..) . o Types of containers for each Pharmaceutical dosage form o Temperature resistance packaging ▪ **Labeling:** o Types of labels &auxiliary labels o Information required on the label	
4.	**Good Practices in production and quality control**	▪ Important Definitions: Pharmaceutical quality assurance (QA), good manufacturing practice, in - process control, Standard operating procedure (SOP), ….. ▪ Principles of GMP; Basic Components of GMP: and GMP requirements. ▪ Good laboratory practice	

(Practical part)

Unit Number	Unit Name	Unit Content	Time Needed
1.	**a.Separation of methyl orange from methylene blue by column chromatography** **b.Separation of Amino acids by thin layer chromatography and paper chromatography**		
2.	**a. Determination of the acid in aspirin by titration .** **b. Determination of Aspirin & pracetamol concentration using spectrophotometer**		
3.	**Determination of the melting point of the following compounds: salicylic acid, benzoic acid , urea, acetanilide, sodium benzoate**		
4.	**Determination of Vit. (C) by iodometric titration method**		

Evaluation Strategies:

	Exams	Percentage	Date
	Mid Exam	**30%**	--/--/----
	Practical part	**20%**	--/--/----
	Final Exam	**50%**	--/--/----

Teaching language:

- English

Teaching Methodology:

- Lectures , Laboratory
- Field visits (QC departments, Jordan food and drug administration)

Text Books & References:

1-Pharmaceutical practice , A.J. Winfield, R.M.E. Richards, 3d. edition, 2005, Churchill Livingstone
2.Joachim Ermer, and John H. McB. Miller (2005), Method Validation in Pharmaceutical Analysis: A Guide to Best Practice, 1st ed., Wiley-VCH.
3. Remington's Pharmaceutical sciences , 14th ,17th ,18th.edition, Mack publishing company
4-Remington ,The science and practice of pharmacy 21st edition,2004, Lippincott William & Wilkens
5- British Pharmacopoeia 2008, British pharmacopoeia Commission, TSO.