Course specification
2017- 2018
Faculty of Pharmacy
Mansoura University

Fourth Level | **Quality control of drugs**

University: Mansoura University (MU)
Faculty: Pharmacy
Department: Pharmaceutical Analytical Chemistry
Course title: Pharmaceutical Analytical Chemistry
Course code: PA 426

Program on which the course is given	B. Pharm
Academic Level	Fourth Level, Second semester, 2017-2018
Date of course specification approval	

1. Basic Information: Course data:

Course title:	**Quality control of drugs**	**Code: PA 426**
Specialization:	**Pharmaceutical**	
Prerequisite:	**Registration**	
Teaching Hours:	**Lecture: 2**	**Practical: 1**
Number of units: (credit hours)	**3**	

2. Course Aims:

2.1. Give the principle and overall definition of quality control, chemical impurities, types and its control, sampling, documentation, recording procedures. Pharmacopoeias monographs, types of methods of analysis, assay tolerances, stability testing of pharmaceuticals (ICH Guidelines), stability indicating assay methods (SIAM), and validation of stability indicating assay and predicted stability.

3. Intended learning outcomes (ILOs):

a- Knowledge and understanding

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

a1	Recall the principles of different analytical techniques for estimation of pharmaceutical compounds
a2	Recall the different analytical methods used for analysis of pharmaceutical compounds using GLP guidelines and validation procedures.
a3	Distinguish appropriate QC criteria to pharmaceuticals.

b- Intellectual skills

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

b1	Propose suitable methods of chemical analysis.
b2	Interpret the experimental data based on relevant chemical and pharmaceutical principles.
b3	Distinguish the physical and chemical properties of chemicals.

c- Professional and practical skills

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

c1	Apply different qualitative and quantitative analytical methods for identification, quality control and estimation of raw materials as well as pharmaceutical preparations.
c2	Analysis and interpret quantitative analytical data.
c3	Apply proper handling and disposal of pharmaceuticals.

d- General and transferable skills

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

d1	Interact effectively in team work
d2	Apply calculations for chemical analysis
d3	Acquire the ability to learn independently
d4	Use calculator stat program to get results of analytical data and validate it.

4. Contents:

Week No	Topics	No. of hours	Lecture credit hours	Practical credit hours
1.	Introduction to Quality control (QC)	2	2	
2.	Chemical Purity of drugs and Official Methods to QC.	2	2	
3.	Specifications of Dosage Forms.	2	2	
4.	Sampling and documentation.	2	2	
5.	Analytical methods of analysis; Gravimetric; Titrimetric, Electrochemical; Molecular Absorption Spectrometry and their applications in drug analysis	2	2	
6.	Analytical methods of analysis; Gravimetric; Titrimetric, Electrochemical; Molecular Absorption Spectrometry and their applications in drug analysis	2	2	

7.	**Mid-term Exam**			
8.	Atomic Absorption spectrometry (AAS) and their application in drug analysis.	2	2	
9.	Atomic Emission Spectrometry(AES) and their application in drug analysis.	2	2	
10.	Validation of analytical methods according to ICH Guidelines.	2	2	
11.	Stability testing of pharmaceuticals according to ICH conditions.	2	2	
12.	Stability indicating assay methods (SIAM)	2	2	
13.	Different methods of analysis of drugs and their degradation products, metabolites, …etc	2	2	
14.	**Resit students Final written & oral**			
15.	**Starting of Final written & oral**			
	Practical topics			
Week No	**Topics**	**No. of hours**	**Lecture credit hours**	**Practical credit hours**
1.	- Pharmacopeial monographs	2		1 hour
2.	- Assay of Glacial Acetic acid	2		1 hour
3.	- Assay of Aspirin in Rivo®Tablets	2		1 hour
4.	- Assay of zinc and Magnesium-content in DF.	2		1 hour
5.	- Assay of iron in Pediatric Ferrous Oral Solution.	2		1 hour
6.	- Assay of nicotinamide in Supraton H® capsules			
7.	**Mid-term Exam**			
8.	- Assay of Hydroxocobalamin in Depovit B_{12}® amp	2		1 hour
9.	- Assay of Naftazone in Raw Materials	2		1 hour
10.	- Assay of Iron in Haemojet® Ampoule - System Sutability Testing in HPLC	2		1 hour
11.	- Validation of Analytical procedures	2		1 hour
12.	**Validation Practical Sheet Exam**	2		1 hour
13.	**Final Practical Exam**	2		1 hour

5. Teaching and learning Methods:

5.1	**Lectures using whiteboard**
5.2	**Lectures using Data show, PowerPoint presentations**
5.3	**Laboratory equipments such as HPLC, TLC plates, potentiometer, spectrophotometer, colorimeter and glasswares.**

6. Student Assessment:

a- Assessment methods

1. Written exam	To assess understanding, intellectual and professional skills
2. Practical exam	To assess professional and practical skills
3. Oral	To assess knowledge, understanding, intellectual skills, general skills and confidence

b- Assessment schedule

Assessment 1	Practical	12th week and 13th week
Assessment 2	Mid-term	7th week
Assessment 3	Oral	15th week
Assessment 4	Written	15th week

c- Weighting of assessments

1.	Mid-term examination	10 %
2.	Final-term examination	50 %
3.	Oral examination	15 %
4.	Practical examination and Semester work	25 %
Total		100 %

7. List of References

No	Reference	Type
1.	Practical course notes prepared by the department staff members	Course notes
2.	Theoretical course Notes “Quality Control of Drugs” prepared by staff members	Course notes
3.	Skoog, D. A. Holler, F. J. and Crouch, S.R. "Principles of Instrumental Analysis". 7th ed., Thomson, Belmont, USA (2016)	Book
4.	Christian, G.D. and O'Reilly, J.E., in "Instrumental Analysis" 6th Ed., Prentice Hall, New Jersy.(٢٠١٣)	Book
5.	Daniel C. Harris. "Quantitative Chemical Analysis". 8th ed., W.H. Freeman and Company, New York, (2010)	Book
6.	Miller JC & Miller JN Statistics and Chemometrics for Analytical Chemistry, 6th edn. Pearson Education Limited: Harlow, England (2010).	Book
7.	Different pharmacopoeias: USP 2016; BP 2016 and EP 2016.	Book
8.	ICH Harmonized Tripartite Guideline, Validation of Analytical Procedures: Text and Methodology, Q2(R1), Current Step 4 Version, Parent Guidelines on Methodology Dated November 6, 1996, Incorporated in November 2005. at: http://www.ich.org/LOB/media/MEDIA417.pdf.	Website
9.	ICH Harmonized Tripartite Guidelines. Stability testing of new drug substances and products, Q1A (R2) (2003). Accessed 25 October 2010 at: http://www.ich.org/LOB/media/MEDIA419.pdf	Website

8. Matrix of knowledge and skills of the course

No	Course contents	Study Week	ILOS			
			Knowledge & understanding	Intellectual skills	Professional and practical skills	General & transferable skills
1.	- Introduction to Quality control (QC). - Chemical Purity of drugs and Official Methods to QC. - Specifications of Dosage Forms. - Sampling and documentation.	1st - 4th	a1, a2, a3	b1	c1	d1, d3
2.	- Analytical methods of analysis; Gravimetric; Titrimetric, Electrochemical; Molecular Absorption Spectrometry and their applications in drug analysis	5th and 6th	a1, a2	b1	c1	d1, d2, d3, d4
3.	- Atomic Absorption spectrometry (AAS) and their application in drug analysis. - Atomic Emission Spectrometry(AES) and their application in drug analysis.	8th and 9th	a1, a2	b1	c1	d1, d3
4.	- Validation of analytical methods according to ICH Guidelines. - Stability testing of pharmaceuticals according to ICH conditions. - Stability indicating assay methods (SIAM) - Different methods of analysis of drugs and their degradation products,and metabolites	10th -13th	a1, a2	b1	c1	d1,d2,d3, d4
5.	Practical: Pharmacopeia, assay of pharmaceuticals and validation of the analytical procedures	1st -6th and 8th -11th	a1, a2, a3	b1, b2, b3	c1, c2, c3	d1, d2, d3, d4

Course Coordinator:	**Prof. Dr. FathAlla FathAlla Belal**
Head of Department:	**Prof. Dr. Yasser El Shabrawy**