Quality control of Drugs

1-Basic Information

Code : PA-525
Level : fifth
Department: Pharmaceutical Analytical Chemistry
Unit : 2 + 1=3 hrs
Lecture : 2 (hrs)/week
Tutorial : (within practical classes)
Practical : 1 (hr) /week
Total : 3(hrs)

2- Aims of Course

1. Explanation of the principles of pharmaceutical quality control and quality assurance of pharmaceutical products and the relation between them as well as teaching students how to apply the principles of good sampling before applying different analytical techniques.
2. Explanation to students how to develop an analytical control laboratory and how to select the suitable method for analysis of drug substances in different matrices.
3. Applying, measuring, evaluating, interpreting and performing the validation parameters and performance criteria for an analytical method.
4. Application of the pharmacopeial methods of stability and stability testing of the drugs.

3- Intended Learning Outcomes of the Course (ILOs)

After successful finishing the course, students should be able to

a- Knowledge and Understanding:

a1- Mention the principles of pharmaceutical quality control and quality assurance of pharmaceutical products..
a3- describes and explain the principles of good sampling and various instruments before applying different analytical techniques and how to select the suitable method for analysis of drug substances in different matrices.
a6- define, describe and explain the pharmacopeial methods of purification, identification and stability testing of the drugs as well as the validation parameters and performance criteria for validation of an analytical method using GLP guidlines

b- Intellectual Skills:

b4- apply the qualitative and quantitative analytical methods for identification, quality control and assay of raw materials as well as pharmaceutical preparations using the

principles of good sampling, and to evaluate & interpret the validation parameters and of the applied analytical method.
bl4-Assess and interpret the possible interactions or interferences of some compounds with the selected method of analysis of certain compounds depending on the studied principles.

c- Professional and practical Skills:

c2- Operate different pharmaceutical instrumentations and laboratory procedures in analysis of drugs in biological samples and use the pharmacopia with regard to the subjects of quality control
c7- handle properly the chemical compounds in the laboratory and be aware of the rules of good laboratory and storage practice to minimize the errors of an applied analytical method.

d- General and Transferable Skills:

d1- Apply the information technology skills, such as word processing and internet communication and online searches.
d9- work effectively with the others as a team work in performing the report on the results of an analytical method.
d12- manage the time in an analytical work effectively.

4- Course Contents

Topic	No. of hours	Lecture	Tutorial / Practical
1. Fundamentals of quality control and quality assurance of pharmaceutical products and the relation between them.	3	2	1
2. Development of an analytical control laboratory	3	2	1
3. Bases of good sampling and storage before applying the analytical procedures	6	4	2
4. Selection of a method of analysis and how to minimize the errors and documentation	6	4	2
5. Validation of an analytical method of analysis	9	6	3
6. Pharmacopeial methods of stability and stability testing of the drugs	12	8	4

5- Teaching and Learning Methods

5.1- Data show
5.2- Blackboard
5.3- Laboratory experiments
5.4- Group discussion problems
5.5- Tutorial discussions

6- Teaching and learning methods for disables

Office hours and specialist workers help them in the laboratory

7- student Assessment

a- Student Assessment methods

7.1-Written mid-term exam to assess al, a3, a6, b4 and b14
7.2- Practical exam to assess c2, c7, d9, d12
7.3- Final exam to assess al, a3, a6, b4 and b14
7.4- 0ral exam to assess al, a3, a6, b4 and b14 7.5- Laboratory report to assess d1

b- Student Assessment Schedule

No.	Assessment	week
1.	Mid-term exam	9
2.	Final practical exam	14
3.	Final term exam	15
4.	Final oral exam	15

c- Weighting of Assessments

No.	Exam.	Mark	%
1.	Mid-Term Exam	10	10
2.	Final Term Exam	50	50
3.	Oral Exam	15	15
4.	Practical Exam (each lab)	10	10
5.	Practical sheet	5	5
6-	Laboratory report (each lab)	10	10
	Total	100	100%

8- List of References

a- Essential Books (Text Books)

Vogels Textbook of Quantitative Inorganic Analysis, 6th Edition Longman Scientific and Technical, USA (1998).
Christian G. D., "Analytical Chemistry ", John-Wiley and Sons, Inc New York (1994).
D. A. Skoog and d. M. west, "Fundamentals of Analytical Chemistry", 7th ed CBS Publishing Asia Itd (2000).

b-Recommended Books

Amer M. M., Pharmaceutical Analytical Chemistry Quantitative Analysis, Cairo.
Fifield & Keal D., Principles & Practice of Analytical Chemistry.

c- Periodicals, Web Sites, etc

The Analyst, J. Pharm. & Biomed. Anal. And J. Assoc. off Anal. Chem

Matrix of the Intended Learning Outcomes (ILOs) of the Course

Week	Topic		K&U	IS	PPS	GTS
	Theoretical	Practical				
1	Fundamentals of quality control and quality assurance of pharmaceutical products and relation between them.	Introduction to Quality control	a1,	b4, b14	c2, c7	d1, d9, d12
2	Fundamentals of quality control and quality assurance of pharmaceutical products and the relation between them.	VOLUMETRIC TITRATIONS Assay of indomethacin capsules (acid-base)	a1, a3	b4, b14	c2, c7	d1, d9, d12
3	Development of an analytical control laboratory	Assay of zinc in Zn containing eye drops (Prisoline Zinc)(complexometry)	a1, a3	b4, b14	c2, c7	d1, d9, d12
4	Fundamentals of good sampling and storage before applying the analytical procedures	Assay of calcium in Ca containing infusions or ampoules(complexometry)	a1, a3	b4, b14	c2, c7	d1, d9, d12
5	Analytical Sampling according to WHO guidelines	Assay of theophylline in Quibron tablets(precipitimetry)	a1, a3	b4, b14	c2, c7	d1, d9, d12
6	Selection of a method of analysis and documentation	Assay of ascorbic acid or iron content of ped.ferrous sulphate oral solution (redox)	a1, a3	b4, b14	c2, c7	d1, d9, d12

Week	Topic		K&U	IS	PPS	GTS
	Theoretical	Practical				
7	Method Development and Validation	UV-SPECTROPHOTOMETRY Assay of chloramphenicol in capsules	a3	b4, b14	c2, c7	d1, d9, d12
8	Method Development and Validation	Assay of ascorbic acid or furosemide (Lasix injection)	a3	b4, b14	c2, c7	d1, d9, d12
9	Mid-Term Exam	SPECTROFLUOROMETRY Analysis of salicylic acid tablets	a3	b4, b14	c2, c7	d1, d9, d12
10	Reference Standards	Spectrofluorometric analysis of ciprofloxacin tablets	a3	b4, b14	c2, c7	d1, d9, d12
11	Stability of Pharmaceuticals	عيد العمال	a3	b4, b14	c2, c7	d1, d9, d12
12	Stability of Pharmaceuticals	FLAME PHOTOMETRY Assay of sodium and potassium in saline infusion	a3	b4, b14	c2, c7	d1, d9, d12
13	Stability Indicating Assays	Practical determinations (Statistical treatment)	a3	b4, b14	c2, c7	d1, d9, d12