



Quality Assurance Unit

Department of Pharmaceutical
Analytical Chemistry



كلية الصيدلة - جامعة أسيوط



Course Specification

Course Specification

1-Basic Information

Title: **Advanced Pharmaceutical Analytical Chemistry** Code: ...

Level : M. Sc. Students

Department: Pharm.Anal. Chem.

Unit: 2hr / week

Lecture: 48hr Tutorial: --- Practical: --- Total: 48hr

2- Aims of Course

Provide the Master student with detailed and updated information on the advanced techniques required to perform the following tasks:

- Analysis of dosage forms.
- Analysis of biological fluids.
- Quality control.
- Statistical analysis of data.
- specific subjects related to the student thesis.

3- Intended Learning Outcomes of Course(ILOs)

a- Knowledge and Understanding:

- a1- Analysis of solid, liquid and aerosol dosage forms.
- a2- Extraction and analysis of drugs in biological fluids.
- a3- Describe the history of quality control, the official compendia, national and international responsibility.
- a4- Defining errors, accuracy, precision, levels of significance, linearity, limits of detection and quantification of analytical methods.

b- Intellectual Skills:

- b1- Selection of a suitable method for the analysis of a certain drug in different dosage forms.
- b2- Propose the required steps for determination of drugs in human plasma and urine.

- b3- Design a method for assessment of the quality of a drug product.
- b4- Finding solutions to the problems encountered during statistical analysis of data.

c- Professional and practical Skills:

- c1- Perform the fundamental steps for analysis of drugs in solid, liquid and aerosol forms.
- c2- Utilizing the tools and equipment applied for analysis of drugs in biological fluids.
- c3- Perform the fundamental steps in drug product quality control.
- c4- Apply the studied statistical techniques and methods.

d- General and Transferable Skills:

- d1- Communication with other colleagues .
- d2- Working in a team through the different steps of analytical procedures.
- d3- Support conclusions by statistical evidence.
- d4- Discuss results with colleagues and base conclusions on scientific basis.

Course Contents

Topic	No. of hours	Lecture	Tutorial / Practical
Analysis of dosage forms			
-Solid dosage forms	4		
- Liquid dosage forms	4		
- Aerosols	4		
Analysis of biological fluids			
- Analysis of drugs in biological fluids	8		
- Official methods for analysis of drugs in biological fluids.	8		
Quality Control	8		
Statistics	6		
Subjects related to student thesis	6		

4- Teaching and Learning Methods

- 4.1- Lectures using power point
- 4.2- Writing a review paper from reference books and periodicals.
- 4.3- Carrying out a net search.

5- Teaching and learning methods for disables

The same as above.

6- student Assessment

a- Student Assessment methods

6.1- Written Exam to assess the theoretical background

b- Student Assessment Schedule

No.	Assessment	week
1.	Written Exam	At the end of course

c- Weighting of Assessments

No.	Exam.	Mark	%
1.	Mid-Term Examination		
2.	Final-Term Examination	100	100
3.	Oral Examination		
4.	Practical Examination		
5.	Semester Work		
6-	<u>Other types of assessment</u>		
	<u>Total</u>	100	100%

7- List of References

a-Course Notes

Students are encouraged to read reference books and periodicals and not to depend on course notes

b- Essential Books (Text Books)

- Analysis of drugs in biological fluids, J. Chamberlain (1985) CRC press, Inc. Boca Raton, Florida.
- Essentials of drug product quality: Concepts and methodology M.M. Abdel-Monem and J.G. Henkel (1978) The C.V. Mosby, pp1-33.
- Quality Control : Theory and application, Bertrand L. Hansen.
- Quality control in pharmaceutical analysis, Z.Deye.
- Quality control in Analytical chemistry, G. Katemann and F. Fljpers (1981) John Wiley&sons, pp1-15.
- United States Pharmacopeia 31 and NF 26, (2008) American Pharmaceutical Association, Washington, DC.
- British Pharmacopoeia (2009) HM Stationary Office, London, UK.
- L.Hamilton, S. Sympson and D. Ellis, Calculations in analytical chemistry (1969) 7th edition, London, UK.

c-Recommended Books

- G. D. Christian " Analytical chemistry ", 6th Ed., John wiley & sons, N. Y., 2003.
- A.A. Siddiqui " pharmaceutical Analysis ", vol.1, CBS publishers & Distributors, New Delhi, 2006.
- D.G. Watson, " Pharmaceutical Analysis ", 2nd Ed., Elsevier, N. Y. 2005

d- Periodicals, Web Sites, etc

Analyst-J. pharmaceutical and Biomedical Analysis, Analytical Letters- Talanta- J. pharm. Sci.- J. chromatography.

8- Facilities Required for Teaching and Learning

.....

Course Coordinator: Prof. Dr. Salwa R. Elshabouri

Head of Department: Prof. Dr. Abdel-Maaboud Ismail Mohamed

Program Coordinator

Date: 9 /10 /2010

University Assiut Course Title Advanced Pharmaceutical Analytical Chemistry
Faculty Pharmacy Course Code.
Department Pharm. Anal. Chem.

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

Week	Topic	Knowledge and Understanding	Intellectual Skills	Professional and Piratical Skills	General and Transferable Skills
1-6	Analysis of dosage forms	a1	b1	c1	d1, d2
7-14	Analysis of biological fluids	a2	b2	c2	d1, d4
15-18	Quality Control	a3	b3	c3	d1, d3
19-21	Statistics	a4	b4	c4	d3, d4
22-14	Subjects related to student thesis	a1, a2	b1-b4	c1- c4	d1, d2, d4

Course Coordinator: Prof. Dr. Salwa R. Elshabouri

Head of Department: Prof. Dr. Abdel-Maaboud Ismail Mohamed

Date: 9 /10 /2010