

Pharmaceutical analytical chemistry-1 (Clinical)

1-Basic Information

Code	: PC 205 Clinical
Level	: First level
Department:	Pharmaceutical Analytical Chemistry
Unit	: 2 + 1=3 (hrs)
Lecture	: two (hrs) /week
Tutorial	: (within practical classes)
Practical	: one (hr) /week
Total	: 3 units (hrs) / week

2- Aims of Course

Explanation of the principles of basic and pharmaceutical analytical chemistry such as fundamentals of acid-base and precipitometric **titrations** as well as the gravimetric analysis, and explaining the application of these principles in the pharmaceutical analysis of drug substances.

Teaching students how to select the suitable method for analysis of drug substances.

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 basic and pharmaceutical analytical chemistry such as fundamentals of acid-base and precipitometric **titrations** as well as the gravimetric analysis and calculation of the basic **statistical** parameters, and explain the application of these principles in the pharmaceutical analysis of drug substances.

a2- Mention the suitable method for analysis of drug substances depending on basic understanding of physico-chemical properties of the chemical compounds.

b- Intellectual Skills:

b1- Assess and interpret the possible interactions or interferences of some chemical compounds with the selected method of analysis of certain compounds depending on the studied principles.

c- Professional and practical Skills:

c1- Handle properly the chemical compounds in the laboratory and be aware of the rules of good laboratory and storage practice to detect easily and 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
Fundamentals of acid-base titrations .	11	7	4
Application of acid-base titrations in the pharmaceutical analysis of drug substances.	10	6	4
Fundamentals of precipitometric titrations	3	2	1
Application of the bases of precipitometric titrations in the pharmaceutical analysis of drug substances.	6	4	2
Fundamentals of gravimetric analysis	6	5	1
Application of gravimetric analysis in the pharmaceutical analysis of drug substances	4	3	1

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 a1-a2 and b14

7.2- Practical exam to assess c7, d9, d12

7.3- Final exam to assess a1-a2, b14, c7

7.4- Oral exam to assess a1-a2, b14 and c7.

7.5- E-learning to assess d1

b- Student Assessment Schedule

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

c- Weighting of Assessments

No.	Exam.	Mark	%
1.	Mid-Term Exam	10	10
2.	Final-Term Exam	50	50
3.	Final Oral Exam	15	15
4.	Final Practical Exam	20	20
5.	Gravimetric Sheet	5	5
	Total	100	100%

8- List of References

Course notes ;

a- Lecture notes and practical notes prepared by staff members of Pharm. Anal. Chem. Dept.

b- 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 Ltd (2000).

c- Recommended Books:

Amer M. M., Pharmaceutical Analytical Chemistry Quantitative Analysis, Cairo.

Fifield & Keal D., Principles & Practice of Analytical Chemistry.

d- Periodicals, Web Sites, etc

The Analyst

J. Pharm. & Biomed. Anal.

J. Assoc. off Anal. Chem.

Course Coordinator: Prof. Horria A. Mohamed

Week	Topic		K & U	IS	PPS	GTS
	Theoretical	Practical				
1	Fundamentals of acid-base titration Theory	Introduction to how to use the tools of analytical work	a1	b14	C7	d1, d9, d12
2	Factors affecting ionization of acid and bases and buffer solutions	Preparation and standardization of HCl Buffer solutions	a1-a2	b14	C7	d1, d9, d12
3	Acid-base titration curves	Titration curves: 1-Strong acid & Strong base 2-Weak acid & Strong base 3-Strong acid & Weak base	a1-a2	b14	C7	d1, d9, d12
4	Application of acid-base titrations	Carbonate&bicarbonate mixture	a1-a2	b14	C7	d1, d9, d12
5	Application of acid-base titrations	Boric acid & borax mixture	a1-a2	b14	C7	d1, d9, d12
6	Application of acid-base titrationsn;;	Determination of BaCl ₂ Biphasic titration (demonstration) Mixture of CaO & CaCO ₃	a1-a2	b14	C7	d1, d9, d12
7	Application of acid-base Non aqueous Titrations	Potassium perulphate Ammonium chloride (Formol titration) Determination of Anitine & aniline salts	a1-a2	b14	C7	d1, d9, d12
8	Applications of precipitimetric Titrations	Mohr s method (for determination of chloride)	a1-a2	b14	C7	d1, d9, d12
9	Applications of precipitimetric Titrations	Volhard s method (for determination of bromide)	a1-a2	b14	C7	d1, d9, d12

Week	Topic		K&U	IS	PPS	GTS
	Theoretical	Practical				
10	Applications of precipitometric Titrations	Mixture of Chloride and iodide dy Fajan s method	a1-a2			
11	Gravimetric analysis, requirements and methods of separations and their applications	Gravimetric determination of Ca	a1-a2	b14	C7	d1, d9, d12
12	Applications of Gravimetric	Gravimetric determination of NI	a1-a2	b14	C7	d1, d9, d12
13		Practical Examination	a1		C7	d1, d9, d12

Pharmaceutical Analytical Chemistry-2 (Clinical)

1-Basic Information

Title: Pharmaceutical Analytical Chemistry-2

Code: PC 306

Credit Hours:

Lectures: 2 / week

Tutorial: Within practical class

Practical: 1 / week

Total: 3 units/week

2- Overall Aims of Course

- a - This course is designed to be an integrative course on Pharmaceutical Analytical Chemistry principles as well as traditional methods of Pharmaceutical Analysis.
- b - The purpose of this course is to give the student insight into different analytical tools and methods as well as selection and use of an analytical method based on strong foundation in the pharmaceutical analytical sciences.
- c - Simple **statistical** treatment and pharmaceutical calculations to ensure proper dealing with analytical data.

3- Intended Learning Outcomes of Course(ILOs)

a- Knowledge and Understanding :

- a1- Learning the basic principles of gravimetric and volumetric analysis, having an appropriate level of knowledge about pharmaceutical analysis & simple **statistics** and gaining the analytical sense in addition to numerical skills.
- a2- Identifying, accessing, organizing and communicating the different principles of studied techniques in both written and oral levels.
- a3- Using the possible technological techniques to support his knowledge.

b- Intellectual Skills

- b1- The ability to calculate the different analytical values e.g. K_{sp} and K_s and having the problem solving skills.
- b2- Combining and applying analytical theories with practical work.
- b3- Selecting the suitable method(s), conditions and reagent(s) for a given compound as well as a mixture of compounds.
- b4- Ability to reflect on and evaluating own performance.
- b5- The student should be willing to challenge current knowledge and thinking.

c- Professional and practical Skills

- c1- This is the second course in a two- semester sequence (the second course is given semester No. (2).) of a laboratory experience that will integrate concepts related to analysis of pure compounds and pharmaceutical products by different methods of analysis, laboratory fundamentals, precautions and limitations.
- c2- The overall design of the course is to provide the student with important analytical skills and experience for both traditional and novel techniques used prior to studying subsequent advanced pharmaceutical sciences.
- c3- After this course is completed, the student should be able to:
- Use different analytical tools and apparatus.
 - Use and apply different analytical procedures for analysis of pure compounds and pharmaceuticals.
 - Select the appropriate analytical technique and tools for a given pharmaceutical compound or mixture of compounds taking into consideration the nature and stability of compounds as well as economical and environmental factors.
 - Participate and function in any analytical group.

d- General and Transferable Skills

- Functioning in a team.
- Using different analytical information for modeling and analyzing given problems.
- Manipulation and sorting of given analytical data.
- Validation and presentation of data in a variety of ways,

4- Course Contents

Topic	Total No. of hours	Lecture	Tutorial / Practical
1. An introduction to Statistics	3	2	1
2. Preceptimetric titrations	8 1/2	6	2 1/2
3. Complexometric titrations	6 1/2	4	2 1/2
4. Redox titrations	15	10	5
5. Gravimetric analysis	9	6	3
Total	42	28	14

5- Teaching and Learning Methods

- Power point presentation
- Overhead projector

- 5.3- Lectures and seminars
- 5.4-Assignment and project works

6- Student Assessment Methods

- 6.1-Mid-Term exam to assess understanding & intellectual skills.
- 6.2-Practical exam to assess professional & practical skills
- 6.3-Oral exam to assess general & transferable skills
- 6.4-Final Term exam to assess knowledge & intellectual skills

Assessment Schedule

Assessment 1.....	week ... 6.....
Assessment 2.....	week ...10.....
Assessment 3.....	week ...13.....

Weighting of Assessments

Mid-Term Examination	10	%
Final-Term Examination	50	%
Oral Examination.	15	%
Practical Examination	25	%
Total	100	%
Any formative only assessment		

7- List of References

Course Notes :

Lecture notes and practical notes prepared by staff members of Pharm. Anal. Chem. Department.

Essential Books (Text Books) :

Vogel, I., "Quantitative Chemical Analysis", Longman Scientific & Technical, 2000.
Christian, G.D., "Analytical Chemistry", John Wiley & Sons, 1994.

Recommended Books

"Quantitative Analysis" by R. A. Day & A. L. Underwood, 3rd Ed., Prentice- Hall, 1974.
"Analytical Chemistry" by G. D. Christian, John- Wiley, New York, 1994.
D.C. Gassatt, the quantitative Analysis of Drug, 2005.

Periodicals, Web Sites,.....etc

- Analyst

- Journal of Pharmaceutical Sciences

8- Facilities Required for Teaching and Learning

Equipped laboratories, Data show, computer and overhead projector.

Instrumental analysis (Clinical)

1-Basic Information

Code	: PC - 407
Level	: 4 th level
Department:	Pharmaceutical Analytical Chemistry
Unit	: 1 + 1=2 (hrs)
Lecture	: one hour /week
Tutorial	: (within practical classes)
Practical	: one (hr) /week
Total	: 2 units (hrs) / week

2- Aims of Course

To provide an overview of spectroscopic, electrochemical and chromatographic techniques appropriate for the modern chemical analysis laboratory.

To develop a basic knowledge of potentiometry, voltametry and chromatography as analytical techniques.

To develop a basic knowledge of spectrophotometry, spectrofluorimetry and atomic spectrometric analytical techniques.

3- Intended Learning Outcomes of the Course (ILOs)

After successful finishing the course, students should be able to

a- Knowledge and Understanding:

- a1- Demonstrate and understand the basic principles of spectroscopic, chromatographic and electrochemical analytical methods.
- a3- Explain different spectroscopic, electrochemical and chromatographic methods and the need for their use in pharmaceutical analysis.
- a6- Give knowledge about applications of spectroscopic, chromatographic and electrochemical methods for pharmaceutical analysis.

b- Intellectual Skills:

- b4- Choose the appropriate spectroscopic methods for the analysis of a material of pharmaceutical relevance.
- b14- Evaluate the validity of the electrochemical, chromatographic and spectrometric methods in the analysis of target compound in complex matrices.

c- Professional and practical Skills:

- c2- Interpretation of spectra, identification and quantification of pharmaceutical compounds.
- c7- Use pH meter, potentiometer, spectrophotometer, spectrofluorometer and flame photometer in the identification and quantification of pharmaceutical compounds.

d- General and Transferable Skills:

- d1- Validate and manipulate given spectra, potentiometric titration curves and chromatograms.
- d9- Participate in a research team or any analytical group for the development of analytical method for analysis of pharmaceutical compounds by spectroscopic, chromatographic or electrochemical methods.
- d13- Solve analytical problems in spectrophotometry, potentiometry and chromatography.

4- Course Contents

Topic	No. of hours	Lecture	Tutorial / Practical
1. Potentiometry	5	3	2
2. Spectrophotometry theory	6	3	3
3. Spectrophotometry applications	4	1	3
4. Spectrofluorimetry	2	1	1
5. Flame emission, atomic absorption and atomic fluorescence spectroscopy.	4	3	1
6. Chromatography	6	3	3

5- Teaching and Learning Methods

- 5.1- Data show
- 5.2- Black and white board
- 5.3- Laboratory experiments
- 5.4- Group discussion problems
- 5.5- Tutorial discussions
- 5.6- Write a report

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-a2 and b14

7.2- Practical exam to assess c7, d9, d12

7.3- Final exam to assess al-a2, b14, c7.

7.4- Oral exam to assess al-a2, b14 and c7

7.5- E-learning to assess d1

b- Student Assessment Schedule

No.	Assessment	week
1.	First assignment	6
2.	Mid-term exam	8
3.	Practical exam	10
4.	Sheet exam.(practical)	13
5.	Final exam	15
6.	Oral exam	15

c- Weighting of Assessments

No.	Exam.	Mark	%
1.	Mid-Term Exam	10	10
2.	Final-Term Exam	50	50
3.	Final Oral Exam	15	15
4.	Final Practical Exam	20	20
5.	Sheet	5	5
	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 Ltd (2000).

Modern Chemical Analysis and Instrumentation”, H.F.Walton &J.Reyes (1980)

Standard Methods of Chemical Analysis” 6th Ed.Vol.3 part 2.

“Quantitative Analysis” 4th Ed. Prentice-Hall, R.A. Day and Jr./A.L. Underwood (1980).

b-Recommended Books

“Quantitative Analytical Chemistry” 4th Ed. Allyn and Bacon, Inc. J.S. Fritz and G.H. Schenk, Boston 1979.

Instrumental Methods of Chemical Analysis” 5th Ed., G.W.Ewing, Mc.Graw-Hill book, New York, 1985.

“Instrumental Methods Of Analysis” 6th Ed. , H.H.Willard, L.L.Merritt, J.A.Dean and F.A. Settle, D.Van Nostrand Co, New York, 1981.

“Atomic Absorption Catalogue”, T.C.Dymott, PyeUnicam Ltd., 2nd Ed. 1981.

“ Principles and practice of Analytical Chemistry” F.W. Fifield and D.Kealey, International textbook Co. Ltd 1975.

Chemistry Experiments for Instrumental Methods” D.T. Sawyer, J.M.Beebe, John Wiley and sons New York 1984.

c- Periodicals, Web Sites, etc

The Analyst

J. Pharm. & Biomed. Anal.

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	Potentiometry	Potentiometric titration of weak acid with strong base	a1, a3,a6	b14	c7	d9, d12
2	Potentiometry	Potentiometric titration of ammonium iron(II) sulphate with standard cerium(IV) sulphate.	a1,a3,a6	b14	c7	d9, d12
3	Spectrophotometry	Absorption spectrum and calibration curve of KMnO ₄ and determination of unknown sample.	a1,a3,a6	b14	c7	d9, d12
4	Spectrophotometry	Determination of copper sulphate	a1,a3,a6	b14	c7	d9, d12
5	Spectrophotometry	Effect of pH on the absorption spectra of thymol blue (visible) and sulfanilamide (UV).	a1,a3,a6	b14	c7	d1, d9, d12
6	Spectrophotometry	Determination of PK _a of methyl orange	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12
7	Spectrophotometry	Determination of molar ratio of iron thiocyanate complex	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12

Week	Topic		K&U	IS	PPS	GTS
	Theoretical	Practical				
8	Spectrofluorimetry	Fluorimetric determination of quinine sulphate	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12
9	Flame photometry	Sodium and potassium in mixture	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12
10	Chromatography	Separation and determination of K ₂ Cr ₂ O ₇ & KMnO ₄ by column chromatography.	a1,a3,a6	b4,b14	c2,c7	d1, d9,
11	Chromatography	TLC separation of a mixture of phenol red and bromophenol blue	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12
12	Chromatography	Analysis of HPLC chart for determination of vitamin Mixture	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12
13	Exam	Practical Examination and sheet	a1,a3,a6	b4,b14	c2,c7	d1, d9, d12

Pharmaceutical analysis and quality control (Clinical)

1-Basic Information

Code	: PCSOS
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

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.

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.

Applying, measuring, evaluating, interpreting and performing the validation parameters and performance criteria for an analytical method.

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 guidelines

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
7. Fundamentals of quality control and quality assurance of pharmaceutical products and the relation between them.	3	2	1
8. Development of an analytical control laboratory	3	2	1
9. Bases of good sampling and storage before applying the analytical procedures	6	4	2
10. Selection of a method of analysis and how to minimize the errors and documentation	6	4	2
11. Validation of an analytical method of analysis	9	6	3
12. Pharmacopeial methods of stability and stability testing of the drugs	12	8	4

5- Teaching and Learning Methods

4.1- Data show

4.3- Laboratory experiments

4.5- Tutorial discussions

4.2- Blackboard

4.4- Group discussion problems

6- Teaching and learning methods for disables

Office hours and specialist workers help them in the laboratory

7- student Assessment

a- Student Assessment methods

6.1-Written mid-term exam to assess a1, a3, a6, b4 and b14

6.2- Practical exam to assess c2, c7, d9, d12

6.3- Final exam to assess a1, a3, a6, b4 and b14

6.4- Oral exam to assess a1, a3, a6, b4 and b14

6.5- 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)**

Vogel's 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 Ltd (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.

J. Assoc. off Anal. Chem

Week	Topic		K&U	IS	PPS	GTS
	Theoretical	Practical				
1	Fundamentals of quality control and quality assurance of pharmaceutical products and the 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(precipitometry)	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 Spectrofluorometric 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		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