

Mansoura University Faculty of Pharmacy Quality Assurance Unit Academic Reference Standards for Postgraduate Programs





Academic Reference Standards (ARS) for Diploma of Quality Control and Drug Analysis program (Analytical Chemistry)

Pharmaceutical Analytical Chemistry Department

ARS

Academic Year: 2021/2022

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Mansoura University Faculty of Pharmacy Quality Assurance Unit Academic Reference Standards for Postgraduate Programs



Diploma of Quality Control and Drug Analysis program PAD 100 Academic Reference Standards (ARS)

The academic reference standard (ARS) for Diploma of Pharmaceutical Sciences program regarding attributes and capabilities of the graduates were based essentially on the General Academic Reference Standards of graduate studies published by National Authority for Quality Assurance and Accreditation of Education (NAQAA 2009) The following specific (ARS) for this program were approved by the faculty council (May 2022).

(Department Council Approval on 11 / 5 /2022)

I.Attributes of the graduate:

The graduates of Quality Control and Drug Analysis program should be able to:

- ✓ Apply their gained knowledge in the field of quality control and drug analysis.
- ✓ Determine professional problems and suggest solutions to them.
- ✓ Master professional skills and use appropriate technological means in the field of quality control and drug analysis.
- ✓ Communicate effectively with health care professionals.
- ✓ Lead work teams in quality control laboratories.
- ✓ Take proper decision using available information regarding methods of analysis.
- ✓ Utilize the available resources efficiently to perform suitable drug analysis.
- ✓ Contribute effectively in environmental conservation and serving the community.
- ✓ Analyze drugs in pharmaceutical industry and work in quality control departments of industry and government.
- ✓ Use reference materials related to drugs.
- ✓ Demonstrate full awareness of ethics in all aspects of quality control.
- ✓ Recognize the need to develop and update their information and engage in continuous learning of advanced analysis methods.
- ✓ Master all traditional and modern techniques used in the field of drug analysis.
- ✓ Apply the scientific thinking approaches and problem-based learning in subjects relevant to quality control and drug analysis.

II.General Standards

1. Knowledge and Understanding:

Upon successful completion of the Program, graduates should be able to:

1.1 Explain the theories and fundamentals of Spectrometry, Quality Control of drugs, Stability of Pharmaceutical Dosage Forms, Microbiological Quality Control, Separation Technique, Electrochemistry, Quality Assurance and Scientific Essay.



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- 1.2 Identify GMP,GLP,QC,QA
- 1.3 Recall the Pharmacy laws and regulations and ethical issue in different quality control areas.
- 1.4 List the basic principles of Food, Nutraceuticals and Cosmetics Analysis,
 Microbiological QC & QA-II, Statistics and Biostatistics or Physical Chemistry as an
 elective course.
- 1.5 Be careful to use the environment friendly procedures in drug analysis and quality control.
- 1.6 Utilize effectively all basic and recent techniques and technological tools used in the field of drug analysis.
- 1.7 Define the principles and basics of quality in professional practice in the fields of quality control
- 1.8 List the basic principles of biological standardization and evaluation of drug activities.
- 1.9 Identify all aspects of quality control of drugs.

2. Intellectual Skills

Upon successful completion of the Program, graduates should be qualified to:

- 2.1 Propose the suitable analytical method for a certain analyte.
- 2.2 Explain the main analytical procedures.
- 2.3 Predict different assays for the evaluation of existing and new drugs.
- 2.4 Discuss microbiological and biochemical basis for determination of body functions and tests.
- 2.5 Analyze and evaluate the gained information in the field of Spectrometry, Quality Control of drugs, Stability of Pharmaceutical Dosage Forms, Microbiological Quality Control, Separation Technique, Electrochemistry, Quality Assurance, and Scientific Essay.
- 2.6 Demonstrate logic and critical way of thinking to suggest solutions for scientific and professional problems according to accompanying circumstances and causes.
- 2.7 Demonstrate creativity and innovative scientific and professional approaches regarding quality control and drug analysis.
- 2.8 Utilize the available professional and scientific resources and research articles to solve problems.
- 2.9 Assess professional and scientific risks in practicing drug analysis
- 2.10 Take professional and scientific decisions based on proofs, evidences and available data.
- 2.11 Participate in comprehensive scientific and professional discussions and communications based on scientific evidence and proofs.



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3. Professionaland Practical Skills

Upon completion of the program, graduates should be able to

- 3.1 Explain the principles and limitations of practical techniques.
- 3.2 Plan analytical methods for determination of pharmaceutical drugs.
- 3.3 Apply different research methodologies and good experimental skills in drug analysis and quality control.
- 3.4 Apply different statistical methods for data analysis and validation.
- 3.5 Manipulate safely and effectively advanced technological research tools and equipments relevant to drug analysis.
- 3.6 Write accurate detailed professional reports for the obtained results in quality control.
- 3.7 Write essay in a scientific and precise way.

4. General and transferable skills:

Upon completion of the program, graduates should be able to:

- 4.1 Acquire effective communication skills with other people.
- 4.2 Manipulate computer program, online database, software and other IT to get information and analyze the obtained data.
- 4.3 Practice self- assessment and learning needed in the field of quality control and drug analysis.
- 4.4 Work effectively in a team and offer expertise and advice to others
- 4.5 Lead a team successfully in familiar professional contexts.
- 4.6 Retrieve information and knowledge from various sources in the field of quality control.
- 4.7 Get maximum use of time to achieve required goals.
- 4.8 Study independently for continuous self-learning and updated knowledge.

Program Coordinator: Head of Department

Head of Department: Prof. Dr. Jenny Jehan Nasr



Mansoura University Faculty of Pharmacy Quality Assurance Unit Diploma of Quality Control and Drug Analysis **Program Specification**

2021/2022

Postgraduate Studies



Program: Diploma in Quality Control and Drug Analysis

Pharmaceutical analytical Chemistry

Department of Pharmaceutical analytical Chemistry

Program Specification

Academic Year: 2021/2022

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Mansoura University Faculty of Pharmacy Quality Assurance Unit of Quality Control and Drug Analys

Diploma of *Quality Control and Drug Analysis*Program Specification
2021/2022



Postgraduate Studies

A-Basic Information

1	Faculty	Pharmacy
2	Program Title:	Diploma in Quality Control and Drug Analysis
3	Program Type:	Multiple
4	Department (s):	Department of Pharmaceutical analytical
		Chemistry, Pharmacology, Pharmaceutics,
		Microbiology.
5	Final award:	Diploma in (specialization)
6	Coordinator:	Head of Department of Pharmaceutical analytical
		Chemistry
7	External Evaluator(s):	Prof. Dr. Hanaa Mohamed Saleh
8	Date of Program	Department council: 11/5/2022
	Specification Approval:	Faculty council: 5/2022

B-Professional Information

1-Program Aims

Upon successful completion of the program, graduates should demonstrate comprehensive knowledge, clear understanding and outstanding skills in pharmaceutical sciences and Quality Control and Drug Analysis

Apply their gained specialized knowledge in the field of quality control and drug analysis.

- 2) Determine professional problems and suggest solutions to them.
- 3) Master professional skills and use appropriate technological means in the field of quality control and drug analysis.
- 4) Communicate effectively with health care professionals.
- 5) Lead work teams in quality control laboratories.
- 5) Take proper decision using available information regarding methods of analysis..
- 6) Utilize the available resources efficiently to perform suitable drug analysis.
- 7) Contribute effectively in environmental conservation and serving the community.
- 8) Analyze drugs in pharmaceutical industry and work in quality control departments of industry and government.
- 9) Use reference materials related to drugs.
- 10) Demonstrate full awareness of ethics in all aspects of quality control.



Diploma of *Quality Control and Drug Analysis*Program Specification 2021/2022



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- 11) Recognize the need to develop and update their information and engage in continuous learning of advanced analysis methods.
- 12) Master all traditional and modern techniques used in the field of drug analysis.
- 13) Apply the scientific thinking approaches and problem based learning in subjects relevant to quality control and drug analysis.

2-Intended Learning Outcomes (ILOs)

A. Knowledge and Understanding:

By the end of this program the graduate should be able to:

A1	Explain the theories and fundamentals of Spectrometry, Quality Control of drugs, Stability of Pharmaceutical Dosage Forms, Microbiological Quality Control, Separation Technique, Electrochemistry, Quality Assurance and Scientific Essay.
A2	Identify GMP,GLP,QC,QA
A3	Recall the Pharmacy laws and regulations and ethical issue in different quality control areas.
A4	List the basic principles of Food, Nutraceuticals and Cosmetics Analysis, Microbiological QC & QA-II, Statistics and Biostatistics or Physical Chemistry as an elective course.
A5	Be careful to use the environment friendly procedures in drug analysis and quality control.
A6	Utilize effectively all basic and recent techniques and technological tools used in the field of drug analysis.
A7	Define the principles and basics of quality in professional practice in the fields of quality control.
A8	List the basic principles of biological standardization and evaluation of drug activities.
A9	Identify all aspects of quality control of drugs.

B. Intellectual Skills

By the end of this program the graduate should be able to:

B1	Propose the suitable analytical method for a certain analyte.
B2	Explain the main analytical procedures.
В3	Predict different assays for the evaluation of existing and new drugs.
B4	Discuss microbiological and biochemical basis for determination of body functions and tests.
B5	Analyze and evaluate the gained information in the field of Spectrometry, Quality Control of drugs, Stability of Pharmaceutical Dosage Forms, Microbiological Quality Control, Separation Technique, Electrochemistry, Quality Assurance, and Scientific Essay.
В6	Demonstrate logic and critical way of thinking to suggest solutions for scientific and professional problems according to accompanying circumstances and causes.



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В7	Demonstrate creativity and innovative scientific and professional approaches regarding quality control and drug analysis.
В8	Utilize the available professional and scientific resources and research articles to solve problems.
В9	Assess professional and scientific risks in practicing drug analysis.
B10	Take professional and scientific decisions based on proofs, evidences and available data.
B11	Participate in comprehensive scientific and professional discussions and communications based on scientific evidences and proofs.

C. Professional and Practical Skills

By the end of this program the graduate should be able to:

C1	Explain the principles and limitations of practical techniques.
C2	Plan analytical methods for determination of pharmaceutical drugs.
C3	Apply different research methodologies and good experimental skills in drug analysis and quality control.
C4	Apply different statistical methods for data analysis and validation.
C5	Manipulate safely and effectively advanced technological research tools and equipments relevant to drug analysis.
C6	Write accurate detailed professional reports for the obtained results in quality control.
C7	Write essay in a scientific and precise way.

D. General and Transferable Skills

By the end of this program the graduate should be able to:

D1	Acquire effective communication skills with other people.
D2	Manipulate computer program, online database, software and other IT to get information and analyze the obtained data.
D3	Practice self- assessment and learning needed in the field of quality control and drug analysis.
D4	Work effectively in a team and offer expertise and advice to others
D5	Lead a team successfully in familiar professional contexts.
D6	Retrieve information and knowledge from various sources in the field of quality control.
D7	Get maximum use of time to achieve required goals.
D8	Study independently for continuous self-learning and updated knowledge.

3-Academic Reference Standards (ARS):

Approved by both the department and faculty councils



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Department Council Approval Date: /5/2022 Faculty Council Approval Date: 5/2022

3a- Academic References Standards: (Attached)

3b-Comparison of provision to External References

Achievement of academic reference standards via program Intended Learning Outcomes.

ILOs	ARS	Program
	2.1.1	A1, A2,A4,A6,A8,A9
1 Vnowledge and Understanding	2,1.2	A3
1. Knowledge and Understanding	2.1.3	A7
	2.1.4	A5
	2.2.1	B1,B3,B4
2. Intellectual Skills	2.2.2	B6,B7,B8
2. Intellectual Skins	2.2.3	B5,B8
	2.2.4	В9
	2.2.5	B10
3. Professional and Practical Skills	2.3.1	C1,C2,C3,C4,C5
	2.3.2	C6, C7
	2.4.1	D1
	4.2	D2
4. General and Transferable Skills	4.3	D3
4. General and Transferable Skins	4.4	D6
	4.5	D4,D7
	4.6	D5
	4.7	D8

Achievement of academic reference standards via program Intended Learning Outcomes.

ILOs	ARS	Program
	1.1	A1, A2, A3, A7, A8, A13
	1.2	A3, A4,A5,A6, A7, A8, A12
1. Knowledge and Understanding	1.3	A1, A8, A13
	1.4	A12
	1.5	A13
	2.1	B1
	2.2	Bb8
2. Intellectual Skills	2.3	В3
	2.4	B6
	2.5	В7
	2.6	B11



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	2.7	В8
	2.8	B13
	2.9	B14
	2.10	B14
	3.1	C1, C2, C3, C4, C9
	3.2	C3
	3.3	C2, C3, C4
3. Professional and Practical Skills	3.4	C5
3. Professional and Practical Skins	3.5	C1, C13
	3.6	C9
	3.7	C10
	3.8	C11
	3.9	C13
	4.1	D1
	4.2	D11
	4.3	D11
	4.4	D3
4. General and Transferable Skills	4.5	D3, D9
	4.6	D8
	4.7	D12
	4.8	D7
	4.9	D2
	4.10	D6, D7

4-Curriculum Structure and Contents

- **a-** The candidate gains his Ph D degree after 50 credit hours of study (8 credit hours of courses and 42 credit hours for thesis).
- **b-** The candidate should study at least 8 credit hours of special courses. The courses will possess the code [300]. These courses include 6 credit hours of obligatory courses, in addition to 2 credit hours of elective courses.
- **c-** The candidate is required to perform research thesis (42 credit hours) in a subject assigned by the supervision committee, endorsed by the department council, the committee of graduate studies & research and the faculty council.
- **d-** The candidate should publish at least one scientific research paper in scientific journals before the approval of a committee of discussion and judgment.



Diploma of *Quality Control and Drug Analysis*Program Specification 2021/2022



Postgraduate Studies

1- Achievement of Program Intended Learning Outcomes via the courses

Comme	С.Н/	Program ILOs (by No.)									
Course	week	K.U*	IS**	P.P.S***	G.T.S****						
		First Se	emester (12 C.H.)								
Spectrometry (PAD -101)	3	A1, A5,A6	B1, B2,B3,B5,B8	C1, C2,C3,C4,C6	D2, D4, D6, D7						
Quality Control of drugs (PAD -102)	3	A1,A2,A3, A5,A6,A7,A9	B1, B2,B3,B5, B8 ,B9	C1, C2,C3,C4,C6	D1, D2, D3, D4, D5,D7,D8						
Stability of Pharmaceutical Dosage Forms (PAD -103)	3	A1,A5,A6,A8	B6,B7,B8	C1, C2, C3,C4,C6	D2,D4,D6,D7, D8						
Microbiological Quality Control (PAD -104)	3	A1,A2,A3,A5 ,A7,A9	B1,B2,B3,B4,B5, B8,B9	C1, C2,C3,C4, C6	D1, D2, D3, D4, D5,D7,D8						
Total	12										
		Second S	Semester (12 C.H.)								
Separation Technique PAD -105	3	A1,A5,A6,A8	B1, B2,B3,B5	C1, C2,C3,C4,C6	D2,D4,D6,D7						
Electrochemistry PAD -106	3	A1,A5,A6	B1, B2, B3,B5,B8	C1, C2,C3,C4,C6	D2,D4,D6,D7						
Quality Assurance	2	A1,A2,A3,A5 ,A7,A9	B1, B2,B5,B9	C1, C2,C3,C4,C6	D1, D2, D3, D4, D5,D7,D8						
Elective course PAD -1EC	2(E)	A1,A4,A5	B6,B7,B8	C4,C6	D2,D4,D6,D7						
Scientific Essay PAD -1SE	2 (E)	A1	B9, B10	C7	D1, D2, D3, D5,D6,D7,D8						
Graduation Project	2										
Total	12										
Total	24										

* Knowledge and Understanding

** Intellectual Skills

*** Professional and Practical Skills

**** General and Transferable Skills



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Codo	Course title		K.U*										IS**		
Code		A1	A2	A3	A5	A6	A7	A8	A9	B1	B2	В3	B5	B8	B9
PAD	Spectrometry	$\sqrt{}$						$\sqrt{}$		$\sqrt{}$		$\sqrt{}$			
(101)		'			V	V		•							
PAD	Quality Control of drugs	$\sqrt{}$		V					1	$\sqrt{}$		$\sqrt{}$			$\sqrt{}$
(102)		•	,	'	'		,		'						•
PAD	Separation Technique							$\sqrt{}$		$\sqrt{}$		$\sqrt{}$			
(105)		V			V	V		V							
PAD	Electrochemistry	V			V	V						V			
(106)		V			V	V									



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e Course title P.P.S***							G.T.S****								
Course title	C1	C2	C3	C4	C6	D1	D2	D3	D4	d5	d6	d7	d8		
Spectrometry	$\sqrt{}$	√	√	V	$\sqrt{}$		√		V			√			
Quality Control of drugs	√	V	V	1	√	V	1	√	√			√	~		
Separation Technique	√	√	√	√	V		1		√		√	7			
Electrochemistry	V	√	√	7	V		1		√			√			
	Quality Control of drugs Separation Technique	Spectrometry Quality Control of drugs Separation Technique Electrochemistry	Spectrometry Quality Control of drugs Separation Technique Electrochemistry	Course title C1 C2 C3 Spectrometry Quality Control of drugs Separation Technique Electrochemistry	Course title C1 C2 C3 C4 Spectrometry $\sqrt{}$ $\sqrt{}$ $\sqrt{}$ $\sqrt{}$ $\sqrt{}$ Quality Control of drugs Separation Technique Electrochemistry	Course title C1 C2 C3 C4 C6 Spectrometry $\sqrt{}$	Spectrometry Quality Control of drugs Separation Technique C1 C2 C3 C4 C6 D1 $\sqrt{}$ \phantom	Spectrometry $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Spectrometry $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Spectrometry $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Course title C1 C2 C3 C4 C6 D1 D2 D3 D4 d5 Spectrometry $\sqrt{}$ $\phantom{a$	Course title C1 C2 C3 C4 C6 D1 D2 D3 D4 d5 d6 Spectrometry $\sqrt{}$ $$	Course title C1 C2 C3 C4 C6 D1 D2 D3 D4 d5 d6 d7 Spectrometry $\sqrt{}$		

** Knowledge and Understanding

** Intellectual Skills

*** Professional and Practical Skills

**** General and Transferable Skills

E Elective course



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6- Student Assessment Methods

- 6.1- Written exam
- 6.2- Oral exam
- 6.3- Practical exam
- 6.4- Graduation Project (Written exam)
- 6.5- Graduation Project (Presentation and discussion)
- 6.4- -----

7- Program Admission Requirements

- 7.1- The candidate should hold a bachelor degree in pharmacy from any Faculty of Pharmacy in Egypt, Arab or foreign countries recognized by the Supreme Council of Universities with minimum general grade of "Good". It is possible to enroll foreign students with general grade "Good" according to the rules determined by the Supreme Council of Universities
- 7.2- The candidate should be available for study at least two days per week throughout the duration of study.
- 7.3- The candidate should follow postgraduate rules of by-law (2014) and its modified by-law (2017) of Faculty of Pharmacy-Mansoura University.

8- Regulations for progression and program completion

- 8.1- The study period is one year of two semesters in addition to the summer semester according to schedules determined by the faculty council.
- 8.2- The faculty council should cancel the student enrollment if he does not gain the diploma degree in 3 years.
- 8.3- The candidate should follow postgraduate rules of by-law (2014) and its modified by-law (2017) of Faculty of Pharmacy-Mansoura University.

9- Facilities Required for Education and Research:

- 9.1- Suitable halls for lectures containing computers, internet and data show.
- 9.2- Library and digital library supplied by recent scientific books and journals.
- 9.3- Laboratories with enough chemicals, apparatus and advanced instruments.
- 9.4- Access to research engines for scientific periodicals in the field of *specialization*.
- 9.5- Sufficient number of staff members, demonstrators and technicians.



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Faculty of Pharmacy
Quality Assurance Unit
Diploma of Quality Control and
Drug Analysis
Program Specification
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10- Graduation project

A graduation project should be prepared by the student for complete fulfillment of the Diploma certificate.

Program Coordinator: Head of Department

Head of Department: Prof. Dr. Prof. Dr. Jenny Jehan Nasr Signature:



Mansoura University Faculty of Pharmacy Quality Assurance Unit Diploma of Quality Control and Drug Analysis Graduation project Specification 2021/2022



Postgraduate Studies



Program: Diploma in Quality Control and Drug Analysis

Pharmaceutical analytical Chemistry

Department of Pharmaceutical analytical Chemistry

Diploma Graduation project Specification

Academic Year: 2021/2022

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Mansoura University Faculty of Pharmacy Quality Assurance Unit Diploma of Quality Control and Drug Analysis Graduation project Specification 2021/2022



Postgraduate Studies

A-Basic Information

1	Faculty	Pharmacy
2	Program Title:	Diploma in Quality Control and Drug Analysis
3	Program Type:	Multiple
4	Department (s):	Department of Pharmaceutical analytical
		Chemistry, Pharmacology, Pharmaceutics, Microbiology.
	Total credits of the	2 C. H.
	Thesis	
	Total credits of the	24 C.H.
	Program	
5	Final award of the	Diploma in Quality Control and Drug Analysis
	Program:	Department of Pharmaceutical analytical Chemistry
6	Coordinator:	Head of Department of Pharmaceutical analytical
		Chemistry
7	External Evaluator(s):	Prof. Dr. Hanaa Mohamed Saleh
8	Date of Program	Department council 11/5/2022
	Specification Approval:	Faculty council: 5/2022

B-Professional Information

1-Aims

The overall aims of the graduation project:

- 1) Apply their gained specialized knowledge in the field of quality control and drug analysis.
- 2) Determine professional problems and suggest solutions to them.
- 3) Master professional skills and use appropriate technological means in the field of quality control and drug analysis.
- 4) Communicate effectively with health care professionals.
- 5) Lead work teams in quality control laboratories.
- 5) Take proper decision using available information regarding methods of analysis..
- 6) Utilize the available resources efficiently to perform suitable drug analysis.
- 7) Contribute effectively in environmental conservation and serving the community.



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- 8) Analyze drugs in pharmaceutical industry and work in quality control departments of industry and government.
- 9) Use reference materials related to drugs.
- 10) Demonstrate full awareness of ethics in all aspects of quality control.
- 11) Recognize the need to develop and update their information and engage in continuous learning of advanced analysis methods.
- 12) Master all traditional and modern techniques used in the field of drug analysis--

2-Intended Learning Outcomes (ILOs)

a. Knowledge and Understanding:

Upon successful completion of the thesis, the graduate should be able to efficiently demonstrate the essential knowledge and understanding of:

A6	a1	Utilize effectively all basic and recent techniques and technological tools used in the field of drug analysis.
A7	a2	Define the principles and basics of quality in professional practice in the fields of quality control.
A8	a3	List the basic principles of biological standardization and evaluation of drug activities.
A9	a4	Identify all aspects of quality control of drugs.

b. Intellectual Skills

By the end of this thesis, the graduate should be able to:

В8	b1	Utilize the available professional and scientific resources and research articles to solve problems.
B9	b2	Assess professional and scientific risks in practicing drug analysis.
B10	b3	Take professional and scientific decisions based on proofs, evidences and available data.
B11	b4	Participate in comprehensive scientific and professional discussions and communications based on scientific evidences and proofs.

c. Professional and Practical Skills

By the end of this thesis, the graduate should be able to:

C3	c1	Apply different research methodologies and good experimental skills in drug analysis and quality control.
C4	c2	Apply different statistical methods for data analysis and validation.
C6	c3	Write accurate detailed professional reports for the obtained results in quality control.



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C7	c4	Write essay in a scientific and precise way.
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d. General and Transferable Skills

By the end of this thesis, the graduate should be able to:

D1	d1	Acquire effective communication skills with other people.
D2	d2	Manipulate computer program, online database, software and other IT to get information and analyze the obtained data.
D4	d3	Work effectively in a team and offer expertise and advice to others
D5	d4	Lead a team successfully in familiar professional contexts.
D6	d5	Retrieve information and knowledge from various sources in the field of quality control.
D7	d6	Get maximum use of time to achieve required goals.

3- Graduation project Contents:

Part	Topics	
1	Abstract (Arabic and English)	
2	Introduction	
3	Aims, Objectives and Rational of the work	
4	Results and Discussion, covering all fields	
5	Methodology	
6	Conclusion	
7	References	

4- Matrix of knowledge and skills of the Graduation project:

Part	Topics	Course ILOs			
rart	Topics	K.U*	IS**	P.P.S ***	G.T.S****
2	Introduction	a1, a2, a3			
3	Objectives/Rational	a4	b1, b2	c1, c2,	d1, d2, d3
4	Results and Discussion		b3	с3	d4, d5
5	Conclusion		b4	c4	d6

^{*} Knowledge and Understanding **Intellectual Skills ***Professional and Practical Skills ****General and Transferable Skills

5. Student Assessment:

A written Graduation project	$\sqrt{}$	
Published Research Paper(s)		
Public Defense		



Mansoura University Faculty of Pharmacy Quality Assurance Unit Diploma of Quality Control and Drug Analysis





Postgraduate Studies

Committee-in-Charge Report	V	
Dept Council Approval	V	

Guidelines of the Thesis (according to By-Law).

- 1- The minimum period for obtaining a PhD is two years from the date of approval of the University's Graduate Studies Council for registration.
- 2- The maximum limit for obtaining a doctoral degree is five years from the date of registration, taking into account cases of suspension of registration, and registration may be extended upon the request of supervisors and the approval of the relevant department council, the Graduate Studies and Research Committee, and the College Board for an academic year with a maximum of two years.
- 3- The student must pass the English Language Examination with the minimum score specified by the University Studies Board to approve the PhD defense date.
- 4- The total number of credit hours for obtaining a doctoral degree is 50 credit hours (8 course hours, 42 credit hours per thesis).
- 5- The student conducts a research on a topic determined by the supervisory committee and approved by the relevant department council and the college, graduate studies and research councils.
- 6- The researcher submits, before registering for the academic degree, the research plan in a public discussion in the department to discuss the topic of the thesis, determine the objectives of the research, the extent of its application, potential problems and how to overcome them.
- 7- After the approval of the Graduate Studies and Research Committee and the College Board, the scientific departments develop specialized courses from code (300) whose number of credit hours does not exceed 8 hours, and their average points are not less than 2.00, and these hours are calculated within the hours prescribed for the program.
- 8- The scientific thesis is the responsibility of the relevant department council and is accomplished scientifically and technically under the responsibility of the supervisory committee. Scientific, technical and administrative support must be provided to the researcher for its completion, and the supervision committee is formed as follows:
- 9- The College Council, upon the proposal of the relevant Department Council, appoints a professor who supervises the thesis (principal supervisor). The council may entrust the supervision of the thesis to one of the assistant professors.
- 10- It is permissible for the supervisors to be many professors or assistant professors, and teachers may participate with a maximum of one in the same specialty.
- 11- A member from abroad who has experience in the specialty to which the dissertation belongs may be joined to the supervision committee.
- 12- The student should meet his main supervisor at least once monthly and a semi-annual report must be provided by the supervisor(s) on the progress of student to the department council and the Graduate Studies Committee and the graduate should be given a copy of the report. The annual report must be submitted to the college council in October each year.
- 13- A postgraduate student registered to obtain a master's degree or a doctorate degree, after completing the thesis preparation, holds a public discussion session on the thesis summary and the



Mansoura University Faculty of Pharmacy Quality Assurance Unit Diploma of Quality Control and Drug Analysis

Graduation project Specification 2021/2022



Postgraduate Studies

results he reached, during which the supervisors determine the extent to which the student fulfills the research point before submitting the thesis to the department council.

- 14- The principal supervisor submits an application that includes a proposal to form a discussion committee and judge the thesis after preparing it and preparing it for discussion in preparation for presentation to the Postgraduate Studies and Research Committee and then the College Board for approval and is supported by the following:
- 15- The report on the validity of the dissertation for discussion, signed by the majority of the members of the supervisory committee, one of whom is the main supervisor.
- 16- A copy of the thesis prepared according to the instructions for writing scientific theses in the faculty.
- 17- At least one research published in a scientific refereed journal.
- 18- The committee for discussion and judgment on the dissertation is formed of three members based on the proposal of the relevant department council, the graduate studies and research committee, and the approval of the college council, one of whom is the main supervisor or two members with one vote. And two other members from among the professors or assistant professors, at least one of them is from outside the college for master's theses, and at least one of them is from outside the university for doctoral theses (the two are from outside the college) according to the text of Article 153 of the Universities Organization Law.
- 19- The department council approves the individual reports, the group report, and what indicates that the student has made the proposed amendments from the discussion and judgment committee and submitted them to the Graduate Studies and Research Committee and the College Board in preparation for presentation to the University Council.
- 20- The date of awarding the academic degree is the date on which the University Council approved the College Board's recommendation for grants.
- 21- The college council, based on the proposal of the discussion and judgment committee, may return the message to the student to correct the errors and complete what the committee deems short of or submit another message in case the thesis is rejected.

6 – Facilities Required:

Library	Library and digital library supplied by recent scientific books and journals.		
Others	Access to research engines for scientific periodicals in the field of <i>Quality Control and Drug Analysis</i>		
	Sufficient number of staff members, demonstrators and technicians		

Thesis Coordinator	Head of Department	Date
Prof. Dr. Head of Department	Prof Dr. Jenny Jehan Nasr	11/5 / 2022

^{*} Date of Dept. Council Approval 5/2022



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality control and drug analysis Diploma Program Quality control of drugs Course Specification (2021/2022)



Dept. of Anal. Chem.

Course Specification

Quality Control Diploma



Quality Control Diploma

Course Specification

Academic year: 2021/2022

البرنامج دبلوم رقابة الجودة والتحليل الدوائي <u>توصيف مقرر</u> الرقابة النوعية للأدوية Quality control of drugs

رئيس القسم أد. جيني جيهان نصر منسق المقرر ا. د. جيني جيهان نصر



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality control and drug analysis Diploma Program





General

Mansoura
Pharmacy
Medicinal Chemistry
Dr. Jenny Jihan Nasr
Diploma of quality control and drug analysis PAD-100
Postgraduate
2021/2022 - First semester
11/5/2022

A.Basic Information: Course data:

Course Title	Drug Regulation
Course Code	PAD-100
Prerequisite	
Teaching Hours: Lecture	عدد الساعات الزمنية
Practical:	عدد الساعات الزمنية
Total Credit Hours	3

B. Professional Information

1- Overall Aims of Course:

- 1- Identify the principle and overall definition of quality control and quality assurance, chemical impurities, types and its control, sampling procedures.
- 2- Recognize Pharmacopoeias monographs, types of methods of analysis, assay tolerances, stability testing of pharmaceuticals (ICH conditions).
- 3- Distinguish stability indicating assay methods (SIAM), and validation of stability indicating assay and predicted stability.

2- Intended Learning Outcomes (ILOs)

a. Knowledge and Understanding

After completion of the course, graduates will be able to

(A2)	a1	Identify the basic principles of different types of quality control.
(A3)	a2	Learn how to write a full report on validation after the analysis of pharmaceutical compounds according to ICH and USP Guidelines.



Mansoura University Faculty of Pharmacy Postgraduate Studies

Quality control and drug analysis Diploma Program



Quality control of drugs Course Specification (2021/2022)

(A1) a3 Describe different stability indicating assay methods (ICH conditions) and QC basics		Describe different stability indicating assay methods (ICH conditions) and QC basics
(A8)	a4	Identify different routes of drug degradation products.

b. Intellectual Skills

After completion of the course, graduates will be able to

Ajier	сотрі	enon of the course, graduates will be able to
(B1)	b1	Specify the main analytical procedures to various related compounds to investigate other possible beneficial modifications.
(B2)	b2	Predict system suitability for the analysis of a given compound in presence of its impurities, metabolites,etc.
(B5)	b3	Conclude a pathway of degradation of certain pharmaceutical compound based on the gained information.
(B6)	b4	Conduct a detailed report about the stability study of pharmaceutical compounds.

c. Professional and Practical Skills

After completion of the course, graduates will be able to

11,000	the completion of the course, graduates will be dote to				
(C6)	c1	Use the available information in pharmacopoeias and monographs.			
(C2)	c2	Utilize the analytical data for active pharmaceutical ingredient and impurities according to ICH Guidelines.			
(C2)	с3	Illustrate degradation pathway and methods of identification or analysis of degradation product.			
(C3)	c4	Apply stability indicating methods on pharmaceutical preparations in the lab.			

d. General and Transferable Skills

After completion of the course, graduates will be able to

(D3)	d1	Present detailed report on degradation and stability of drugs and pharmaceutical dosage forms
(D2)	d1	Present data on analysis of pharmaceutical samples
(D2)	d2	Use computer statistical programs to get results of analytical data and validate it
(D1)	d3	Implement oral presentations and scientific discussions.

3. Course Contents

Week No.	Topics	Lecture Hours	Practical / Tutorial hr.
1	Specification and test methods, assay tolerance impurities, types. Part 1	2	2
2	Specification and test methods, assay tolerance impurities, types. Part 2	2	2



Mansoura University Faculty of Pharmacy Postgraduate Studies

Quality control and drug analysis Diploma Program Quality control of drugs Course Specification



(2021/2022)

3	Quality control and quality assurance. Part 1	2	2
4	Quality control and quality assurance. Part 2	2	2
5	Sampling and how to write and read report.	2	2
6	Analytical method development, types of methods and validation according to ICH Guidelines.	2	2
7	Stability of drugs, Different degradation routs of drugs including hydrolysis oxidation, photooxidation,	2	2
8	Stability testing of pharmaceuticals according to ICH conditions.		2
9	Stability indicating assay methods (SIAM)	2	2
10	Stability indicating assay methods (SIAM)		2
Total: 11 weeks		20	20

4- Matrix of knowledge and skills of the course (contents versus ILOs of the course)

Week	Topics	Course ILOs			
,, con	Topios	K.U*	IS**	P.P.S***	G.T.S****
1	Specification and test methods, assay tolerance impurities, types.	a1-a4	b1,b2,b3	c1,c2	d1, d2, d3
2	Quality control and quality assurance	a1, a2,a4	b2, b4	c1, c2, c3	d1, d2
3	Sampling and how to write and read report. Analytical method development, types of methods and validation according to ICH Guidelines.	a4, a5	b1, b2	c1, c2,c3	d1, d2, d3
4	Stability of drugs, Different degradation routs of drugs including hydrolysis oxidation, photooxidation,	a1, a2	b1, b2, b3	c1,c2	d1, d2, d3
5	Stability testing of pharmaceuticals according to ICH conditions. Stability indicating assay methods (SIAM)	a1, a2,a4	b2, b4	c1, c2, c3	d1, d2

^{*} Knowledge and Understanding

^{**}Intellectual Skills

^{***}Professional and Practical Skills

^{****}General and Transferable Skills



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality control and drug analysis Diploma Program



Quality control of drugs Course Specification (2021/2022)

5- Teaching and Learning Methods:

5.1	Lectures using Power Point (PPT) presentations
5.2	Lectures using whiteboard
	Video-recorded lectures, uploaded to the University Portal for Online learning
	Activities and tasks required to develop students' self-learning skills.
	Tutorial, Class Activity and Group Discussion to explain what has not been understood
	Interactive Sessions using Microsoft Teams
	Internet search and Research Assignments to design Formative Assignments
	Practical Training / Laboratory
	Seminar / Workshop

6- Student Assessment:

	Assessment Methods		Assessment Schedule	Weighing of Assessments
Assessment 1	Written Exam	Paper exams that are corrected	Last weak	70%
	(Final)	electronically and/or manually.		7 0 7 0
		To assess understanding,		
		intellectual, professional skills		
Assessment 2	Tutorial / or	Assignments prepared by	9 th weak	20%
	Practical	students and sent to the		
	assignments	supervisor electronically for		
	and Semester	evaluation. To assess		
	work	professional skills		
Assessment 3	Oral Exam	To assess understanding,	Last weak	10%
		intellectual skills, General and		
		Transferable skills		
				100 %

7- List of References

	Reference	Type
1.	Different pharmacopoeias: USP, BP and EP.	Essential Book (Text Books)
2.	Beckett, A. H. & Stenlake, J. B. "Practical Pharmaceutical Chemistry" Part I&II, 4th Ed., Athlone Press London.	
3.	Christian, G.D. and O'Reilly, J.E., in "Instrumental Analysis" 6th Ed., Prentice Hall, New Jersy (2013).	



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality control and drug analysis Diploma Program



Quality control and drug analysis Diploma Frogra

Quality control of drugs Course Specification

(2021/2022)

4	4.	Miller JC & Miller JN (2005) Statistics and Chemometrics for Analytical Chemistry, 5th edn. Pearson Education Limited: Harlow, England, pp 256.	
5	5.	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	websites

8- Facilities required for teaching and learning

-Class room	Data show- Computers, Internet
- Laboratory facilities	Microscopes, equipment, tools
Others	Software.

9. Signature

Course Coordinator	Head of Department	Date
Prof. Dr. Jenny Jehan Nasr	Prof Dr. Jenny Jehan Nasr	

^{*} Date of Dept. Council Approval 5/2022



Postgraduate Studies





Department of Pharmaceutical Analytical Chemistry

Program: Diploma of quality control and drug analysis (Pharmaceutical Analytical Chemistry)

Course: Quality control of drugs Code: (PAD-102)

Academic year: 2021/2022 First Semester

البرنامج دبلوم رقابة الجودة والتحليل الدوائي <u>تقرير مقرر</u> رقابة الجودة للأدوية

رئيس القسم أ.د. جيني جيهان محمد نصر

منسق المقرر أ.د. جيني جيهان محمد نصر



Postgraduate Studies



University: Mansoura University

Faculty: Pharmacy

Department: Pharmaceutical Analytical Chemistry

A. Basic Information

Course Title and code:	Quality control of drugs PAD-102
Program on which this course is given:	Diploma of quality control and drug analysis (Pharmaceutical Analytical Chemistry)
Total Credit hours:	3
Lectures:	Tutorial/Practical:
Academic Level	Postgraduate
Academic year	2021/2022- first semester
Name of lecturers contributed to the delivery of this course	 Prof Dr Jenny Jeehhan Mohamed Nasr Assoc Prof Dr Fawzi Abdalla Elsebaei
Course co-coordinator:	Prof Dr Jenny Jeehhan Mohamed Nasr
External evaluator:	Prof Dr Hanaa Mohamed Saleh
Date of Department Council Approval	مجلس قسم 11/5/2022
Date of Faculty Council Approval	مجلس كلية شهر مايو 2022

B. Statistical Information:

No. of students attending the course: 21 No. of students completing the course: 18

Exam Results

Passed No.: 13 percentage: 61.9 Failed No.5 percentage: 23.81

Grading of successful students (%):

\mathbf{A} +	7.69	A	7.69	A-	-
\mathbf{B} +	7.69	В	30.77	В-	-
C+	-	C	15.38	C-	15.38
D +	-	D	15.38	D-	-





Postgraduate Studies

C. Professional Information:

1. Course teaching:

No.	Topics actually taught
1.	Definition and terminology, quality control and quality assurance, objectives and steps of quality control, total quality management,
2.	impurities, types, requirements for control of impurities
3.	Sampling facilities, purposes, methods and procedure.
4.	Documentation, standard operating procedures, writing and reading quality control report,
5.	Official methods of analysis, validation of analytical procedures,
6.	Stability of drugs in their dosage forms, routes of drug degradation (hydrolysis, decarboxylation, elimination, autoxidation, photodegradation,), mechanisms of drug degradation, strategies for controlling drug degradation
7.	Stability of drugs in their dosage forms, routes of drug degradation (hydrolysis, decarboxylation, elimination, autoxidation, photodegradation,), mechanisms of drug degradation, strategies for controlling drug degradation
8.	Stability of drugs in their dosage forms, routes of drug degradation (hydrolysis, decarboxylation, elimination, autoxidation, photodegradation,), mechanisms of drug degradation, strategies for controlling drug degradation
9.	Guidelines for stability testing, forced degradation studies
10.	Development & optimization of stability indicating HPLC Method

Topics taught as a percentage of the content specified:

√ > 90 %	70 - 90 %	< 70 %
----------	-----------	--------

Lecturers commitment of the course content:

,		
√ > 90 %	70 - 90 %	< 70 %

Coverage of exam topics to course content:

√ > 90 %	70 - 90 %	< 70 %
----------	-----------	--------

2. Used teaching and Learning Methods:

Lectures:	$\sqrt{}$
Computer aided learning:	V
a- On line learning through my mans "Mansoura university "as	
recorded – video lectures"	
b- Inter active discussion through My Mans	





Postgraduate Studies

Practical Training/ Laboratory:	$\sqrt{}$
Seminar / Work shop:	$\sqrt{}$
Class Activity:	$\sqrt{}$
Case Study:	$\sqrt{}$
Other assignments / home work:	

3. Student Assessment:

a. Method of Assessment	Percentage of total
Written examination	70
Oral examination	10
Practical / laboratory work	20
Semester Work	

b. Members of examination committee:

- 1. Prof Dr Jenny Jeehhan Mohamed Nasr
- 2. Assoc Prof Dr Fawzi Abdalla Elsebaei

c. Role of external evaluator (If any):

- 1. Revision of course contents, and suggest new topics.
- 2. Revision of teaching and learning strategy.
- 3. Revision of course notes and suggest enhancement plan
- 4. Revision of Exam and related assignments

4. Facilities and Teaching Materials

Totally adequate	\checkmark
Adequate to some extent	
Inadequate	
List any inadequacies:	

5. Administrative constraints

List any difficulties encountered:		





Postgraduate Studies

6. Student evaluation of the course:

List any criticisms and response of course team

criticisms	response of course team

7. Comments from external evaluator(s) (if exists) and response of course team:

Comment	Response

8. Course enhancement suggestions:

Progress on actions identified in the previous year's action plan:

Action	Completed	Not completed	Why not completed?
Upgrade course note	V		

9. Action plan for academic year 2021 - 2022:

Action Required	Person responsible	Completion Date
Upgrade course note	 Prof Dr Jenny Jeehhan Mohamed Nasr Assoc Prof Dr Fawzi Abdalla Elsebaei 	9/2021

	Name	Signature
Course Coordinator	Prof Dr Jenny Jeehhan Mohamed Nasr	
Head of Department	Prof Dr Jenny Jeehhan Mohamed Nasr	



Mansoura University Faculty of Pharmacy Quality Assurance Unit Course Report 2021/2022 Postgraduate Studies





Department of Pharmaceutical Analytical Chemistry

Program: Diploma of quality control and drug analysis (Pharmaceutical Analytical Chemistry)

Course: Spectrometry Code: (PAD-101)

Academic year: 2021/2022 First Semester

البرنامج دبلوم رقابة الجودة والتحليل الدوائى

> رئيس القسم ۱. د. جيني جيهان محمد نصر

<u>تقرير المقرر</u> القياسات الطيفية Spectrometry

منسق المقرر ۱. م.د. زينب شريبه







University: Mansoura University

Faculty: Pharmacy

Department: Pharmaceutical Analytical Chemistry

A. Basic Information

Course Title and code:	Spectrometry- PAD-301	
Program on which this course is given:	Diploma of quality control and drug analysis (Pharmaceutical Analytical Chemistry)	
Total Credit hours:	3	
Lectures: 2	Tutorial/Practical: 1	
Academic Level	Postgraduate	
Academic year	2021/2022- First semester	
Name of lecturers contributed to the delivery of this course	 Assoc. Prof. Dr. Zeinab Sheribah Dr. Rasha Ahmed AboShabana 	
Course co-coordinator:	Assoc. Prof. Dr. Zeinab Sheribah	
External evaluator:	Prof. Dr. Mokhtar Mabrouk	
Date of Department Council Approval	11/5/2022	
Date of Faculty Council Approval	5/2022	

B. Statistical Information:

No. of students attending the course: 21 No. of students completing the course: 18

Exam Results

Passed No.: 16 percentage: 76.19
Failed No.:2 percentage: 9.52

Grading of successful students (%):

A +	2	A	3	A-	
B +	-	В	3	В-	-
C +	3	C	1	C-	3
D +	-	D	1	D-	-

C. Professional Information:



Postgraduate Studies



1. Course teaching:

No.	Topics actually taught	
1.	Absorption spectrophotometry: Beer-lambert law, its applications (problems), and its deviation	
2.	Spectrophotometric applications and determination of pharmaceuticals	
3.	Fluorescence and phosphorescence spectrometry	
4.	Fluorescence quenching, applications, derivatization, synchronous and derivative	

Topics taught as a percentage of the content specified:

√ > 90 %	70 - 90 %	< 70 %
----------	-----------	--------

Lecturers commitment of the course content:

Coverage of exam topics to course content:

√ > 90 %	70 - 90 %	< 70 %

2. Used teaching and Learning Methods:

Lectures:	
Computer aided learning: a- On line learning through my mans "Mansoura university "as recorded – video lectures"	√
b- Inter active discussion through My Mans	
Practical Training/ Laboratory:	
Seminar / Work shop:	
Class Activity:	
Case Study:	√
Other assignments / home work:	

3. Student Assessment:

a. Method of Assessment	Percentage of total
Written examination	70
Oral examination	10
Practical / laboratory work	20



2021/2022 Postgraduate Studies



Semester Work		
b. Members of examination committe	e:	
1. Assoc. Prof. Dr. Zeinab Sheribah		
2. Dr. Rasha Ahmed AboShabana		
D. L. C. A. L. L. A. (IC.)		
c. Role of external evaluator (If any):	goet n	avy tanias
1. Revision of course contents, and sug2. Revision of teaching and learning str	_	-
3. Revision of course notes and suggest		
4. Revision of Exam and related assignment		recinent plan
4. Facilities and Teaching Materials	3	
Totally adequate	√	
Adequate to some extent		
Inadequate		
List any inadequacies:		
5. Administrative constraints		
List any difficulties encountered:		
C C(1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
6. Student evaluation of the course:		
List any criticisms and response of cou	irse te	
criticisms		response of course team
7. Comments from external evaluate	or(s)	(if exists) and response of course team:
Comment	(-)	Response

8. Course enhancement suggestions:

Progress on actions identified in the previous year's action plan:





Postgraduate Studies

Action	Completed	Not completed	Why not completed?
Upgrade course note			

9. Action plan for academic year 2021 - 2022:

Action Required	Person responsible	Completion Date
Upgrade course note	Assoc. Prof. Dr. Zeinab Sheribah	2021/2022

	Name	Signature
Course Coordinator	Assoc. Prof. Dr. Zeinab Sheribah	
Head of Department	Prof. Dr. Jenny Jeehan Mohamed Nasr	



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality Control and Drug Analysis Diploma Program Spectrometry Course Specification (2021/2022)



Dept. of Pharmaceutical	Course	Quality Control and
Analytical Chemistry	Specification	Drug Analysis Diploma



Quality Control and Drug Analysis Diploma

Course Specification

Academic year: 2021/2022

البرنامج دبلوم رقابة الجودة وتحليل الادوية <u>توصيف مقرر</u> القياسات الطيفية Spectrometry

رئيس القسم ا. د. جيني جيهان نصر منسق المقرر ا. م.د. زينب شريبه



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality Control and Drug Analysis Diploma Program Spectrometry Course Specification

(2021/2022)



General

University	Mansoura
Faculty	Pharmacy
Department offering the course	Pharmaceutical Analytical Chemistry
Department supervising the course	Assoc. Prof. Dr. Zeinab Sheribah
Program on which the course is given	Quality Control and Drug Analysis Diploma
	Program
Academic Level	Postgraduate
Academic year	2021/2022 - First semester
Date of course specification approval	11/5/2022

A.Basic Information: Course data:

Course Title	Spectrometry
Course Code	PAD-101
Prerequisite	
Teaching Hours: Lecture	2
Practical:	2
Total Credit Hours	3

B. Professional Information

1- Overall Aims of Course:

- 1- Demonstrate the basic concepts of UV/Vis spectroscopy, fluorescence and phosphorescence spectrometry, flame emission and atomic absorption spectroscopy, infrared spectrometry, nuclear magnetic resonance spectroscopy, and mass spectrometry.
- 2- Recognize the instrumentation and the applications of these methods to pharmaceutical compounds.

2- Intended Learning Outcomes (ILOs)

a. Knowledge and Understanding

After completion of the course, graduates will be able to

<u> ijici</u>	After completion of the course, graduates will be dole to				
(A1)	a1	Recognize in-depth and breadth the fundamentals of different spectrometric techniques.			
(A5)	a2	Identify the recommended environment friendly procedures employed in spectrometric analysis of pharmaceutical compounds.			
(A6)	a3	Classify the basic and recent spectrometric techniques used in the field of drug analysis.			
	a4	Illustrate the interpretation of the results obtained after the spectroscopic analysis of pharmaceutical compounds.			



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality Control and Drug Analysis Diploma Program





b. Intellectual Skills

After completion of the course, graduates will be able to

(B1)	b1	Select the proper spectroscopic analytical method for the determination of a given pharmaceutical compound.	
(B2)	b2	Create detailed reports about the analysis of pharmaceutical compounds.	
(B3)	b3	Predict different spectrometric assay methods for the evaluation of existing and new drugs.	
(B5)	b4	Analyze and evaluate the gained information in the field of spectrometry.	
(B8)	b5	Solve problems using the available professional and scientific resources and research articles.	
	b6	Conduct suitable chemical derivatization methods to various pharmaceutical compounds to suit different spectroscopic techniques.	

c. Professional and Practical Skills

After completion of the course, graduates will be able to

(C1)	c1	Illustrate the principles and limitations of practical spectrometric techniques.				
(C1)	c2	Operate available instruments such as UV/Vis spectrophotometer and spectrofluorometer.				
(C2)	c3	Design spectrometric analytical methods for determination of pharmaceutical compounds.				
(C3)	c4	Apply different research methodologies and good experimental skills in drug analysis.				
(C4)	c5	Apply different statistical methods for data analysis and validation.				
(C6)	с6	Design a detailed professional report for the obtained results.				

d. General and Transferable Skills

After completion of the course, graduates will be able to

(D2)	(D2) d1 Manipulate computer program, online database, and software to get information and analyze the obtained data.			
(D4)	d2	Work effectively in a team and offer expertise and advice to others.		
(D6)	d3	Retrieve information and knowledge from various sources in the field of quality control.		



Mansoura University Faculty of Pharmacy Postgraduate Studies

Quality Control and Drug Analysis Diploma Program Spectrometry Course Specification



(2021/2022)

3. Course Contents

Topic	Topics	Lecture	Practical /
No.	·	Hours	Tutorial hr.
1	UV/vis spectroscopy: Definitions,	2	2
	properties, instrumentation		
2	Absorption spectrophotometry: Beer-lambert law, its applications (problems), and its deviation	2	4
3	Background correction methods	2	-
4	Spectrophotometric applications and determination of pharmaceuticals	4	8
5	Fluorescence and phosphorescence spectrometry	2	-
6	Fluorescence spectrometry: factors and instrumentation	2	2
7	Fluorescence quenching, applications, derivatization, synchronous and derivative	4	6
8	Chemiluminescence	2	-
9	Atomic spectrometry, NMR, IR	2	-
Total: 11 weeks		22	22

4- Matrix of knowledge and skills of the course (contents versus ILOs of the course)

Week	Topics	Course ILOs			
VV CCR	Topics	K.U*	IS**	P.P.S***	G.T.S****
1	UV/Vis spectroscopy: Definitions, properties, and instrumentation	a1	-	c1, c2	d1, d3
2	Absorption spectrophotometry: Beerlambert law (Applications and Deviations)	a1	b5	c1	d1-d3
3	Background correction methods	a1	b5	c1	d1
4,5	Spectrophotometric applications and determination of pharmaceuticals	a1-a4	b1, b2,b6	c2, c3, c5	d1-d3
6	Fluorescence and phosphorescence spectrometry (Fundamentals)	a1	b1	c1, c2	d1
7	Fluorescence spectrometry: factors and instrumentation	a1	b1, b3	c1, c2	d1, d3
8,9	Fluorescence quenching, applications, derivatization, synchronous and derivative	a1-a4	b1-b6	c2-c6	d1-d3
10	Chemiluminescence	a1,a3	b1, b3	-	d3
11	Atomic spectrometry, NMR, IR	a1,a3	b1,b3	-	d3

^{*} Knowledge and Understanding ****General and Transferable Skills

5- Teaching and Learning Methods:

^{**}Intellectual Skills

^{***}Professional and Practical Skills



Mansoura University Faculty of Pharmacy Postgraduate Studies Quality Control and Drug Analysis Diploma Program Spectrometry Course Specification



(2021/2022)

5.1	Lectures using Power Point (PPT) presentations
5.2	Lectures using whiteboard
5.3	Video-recorded lectures, uploaded to the University Portal for Online learning
5.4	Activities and tasks required to develop students' self-learning skills.
5.5	Tutorial, Class Activity and Group Discussion to explain what has not been understood
5.6	Interactive Sessions using Microsoft Teams
5.7	Internet search and Research Assignments to design Formative Assignments
5.8	Practical Training / Laboratory
5.9	Seminar / Workshop

6- Student Assessment:

	Assessment		Assessment	Weighing of
	Methods		Schedule	Assessments
Assessment 1	Written Exam	Paper exams that are corrected	Week 15	70 %
	(Final)	electronically and/or manually.		
		To assess understanding,		
		intellectual, professional skills		
Assessment 2	Tutorial / or	Assignments prepared by	Week 13	20 %
	Practical	students and sent to the		
	assignments	supervisor electronically for		
	and Semester	evaluation. To assess		
	work	professional skills		
Assessment 3	Oral Exam	To assess understanding,	Week 15	10 %
		intellectual skills, General and		
		Transferable skills		
				100 %

7- List of References

	Reference	Type
1.	Quantitative Chemical Analysis, Daniel C. Harris, 8th edition, 2010, W. H. Freeman & Co., New York, ISBN: 9781429218153	Textbook
2.	Christian, G.D. and O'Reilly, J.E., in "Instrumental Analysis" 6th Ed., Prentice Hall, New Jersy (2013).	Textbook
3.	Principles of Instrumental Analysis (6th ed), Douglas A. Skoog, F. James Holler and Stanley R. Crouch, Brooks Cole, 2007.	Textbook
4.	Pharmaceutical Analysis Textbook for Pharmacy Students and Pharmaceutical Chemists, 3rd Edition ,2008, Academic Press, Ahuja & Jimidar, David G. Watson, 2012, Churchill Livingstone.	Textbook



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5.	Modern Analytical Chemistry, David Harvey, McGraw-Hill, 1st ed, 2000, ISBN: 0-07-237547-7	Textbook
6.	Chemical Analysis: Modern Instrumentation Methods and Techniques, Francis Rouessac, AnnickRouessac, John Wiley & Sons, 2nd ed, 2007.ISBN: 0470859040, 9780470859049	Textbook

8- Facilities required for teaching and learning

-Class room	Data show- Computers, Internet
- Laboratory facilities	Equipment, Chemicals and Reagents, Laboratory Glassware
- Library	Textbooks

9. Signature

Course Coordinator	Head of Department	Date
Assoc. Prof. Dr. Zeinab Sheribah	Prof Dr. Jenny Jehan Nasr	

^{*} Date of Dept. Council Approval:/ 5/2021