Academic Reference Standards (ARS)
For
Quality Control Diploma
(Pharmaceutics)

Name of the Dept. Pharmaceutics

ARS

Academic Year: 2021/2022

Head of Department

Prof. Dr. Irhan Ibrahim Abu Hashim

Quality Control Diploma (Pharmaceutics)

Academic Reference Standards (ARS)

(Department Council Approval on 15/5/2022)

(Faculty Council Approval on 5/2022)

Quality Control Diploma

This programme is designed to enable the students to gain information about compounding, preservation and storage of different dosage forms Also, to contribute the overall training of postgraduate pharmacy students in the area of solving practical problems on drug release from various dosage forms as well as the factors influencing rate and extent of drug release. Research projects have typically involved, the formulation, compounding, preservation and storage of different dosage forms including oral dosage forms, rectal preparations, topical preparations and parental preparations. Also, proportions of some useful pharmaceutical excipients are included. This program provide the students with the fundamental knowledge and skills to enhance career opportunities within the pharmaceutical industries, academic pharmaceutical research and pharmaceutical regulatory organizations. Also, provide the students with the concept of pharmaceutical dosage forms, its preparation and evaluation. This program, provide the postgraduate students with basic principles of pharmaceutical engineering, manufacturing pharmacy and how to deal with different unit operation and unit processes. While our program offers an experimental education curriculums, our students also benefit from our research facilities.

I. Attributes of the graduate:

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

1. Implement basic methodologies of scientific research in the field of pharmaceutics including; Stability calculation, Interpretation of kinetic data, Hydrolysis and other acyl transfers oxidation, Reaction kinetics, Complexation and bioavailability, In-process quality control, Finished product control, quality control during packaging operations Control and

assurance of finished products

2. Master the principles of pharmaceutical stability and Storage technology.

3. Adopt the critical and analytical thinking approaches in subjects relevant to different drug delivery systems.

4. Integrate the knowledge in the fields of pharmaceutical stability and Storage technology with other relevant knowledge.

5. Show considerable awareness regarding the current problems and the recent theories and trends in the field of pharmaceutical stability and packaging systems.

6. Design of small market equipments represented to each unit of operation.

7. Understand the different details of quality principles, quality parameters and Good Manufacturing Practice Elements (GMP).

8. Master the major concepts in management and marketing to the different fields of pharmacy practice.

9. Understand the different application involved in different management system.

II. General Standards

1. Knowledge and Understanding:

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

1.1 Define the basic stability concepts of pharmaceutical dosage forms and quality Assurance.

1.2 Describe the importance of quality management and good manufacturing practice (GMP).

1.3 Identify the procedure of storage of any dosage forms and the technology of packaging.

1.4 Summarize the quality control of each pharmaceutical operation and how to minimize the error of manufacturing, storage & handling.

1.5 State the adequate selling skills needed in the pharmaceutical markets.

1.6 Summarize the proper management of pharmaceutical services in a community pharmacy.

1.7 State methods to determine the important physicochemical properties of the materials

used in dosage form design.

2. Intellectual Skills

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

2.1. Evaluate information in the fields of stability of pharmaceutical dosage forms and quality Assurance.

2.2. Develop deductions and conclusions based on provided pharmaceutical information.

2.3. Outline the preparations of different pharmaceutical stability.

2.4. Explain the different theory of unit operation and the class of dosage form stability.

2.5. Categorize all equations used in Stability calculation, Interpretation of kinetic data, Hydrolysis and other acyl transfers oxidation, Reaction kinetics, Complexation and bioavailability.

3. Professional and Practical Skills

Upon completion of the program, graduates should be able to

3.1. Perform certain professional skills in the fields of Stability of pharmaceutical dosage forms and quality Assurance.

3.2. Evaluate professional reports regarding pharmaceutical procedure, obtained data and results.

3.3. Use and evaluate different laboratory tools in the field of pharmaceutical stability.

3.4. Handle safely the materials used in research taking into account their physical and chemical properties, including any specific hazards associated with their use.

3.5. Experiment the preparation procedures and the different methods of evaluation and determination of physicochemical properties of materials.

3.6. Write structured reports including graphical material and give oral presentations.

3.7. Recognize the suitable methodology to operate the different equipment.

3.8. Discuss the basic concepts of management and marketing to pharmacy students.

3.9. Take professional decisions regarding quality control, packaging operations, and stability of drugs.

4. General and transferable skills:

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

4.1. Communicate effectively with colleagues in the field of Stability of pharmaceutical dosage forms and quality Assurance.
4.2. Apply gained information to solve the problems encountered in the manufacture of dosage forms

4.3. Utilize effectively different available information resources relevant to pharmaceutics.

4.4. Implement continuous and lifelong self-learning about pharmaceutics.

4.5. Adapt independent learning ability required for continuing research in the field of Stability of pharmaceutical dosage forms and quality Assurance.

4.6. Dissiminate the application of GMP.

Program: Quality Control Diploma

Pharmaceutics Department

Program Specification

Academic Year: ***2021/2022***

Head of Department

Prof. Dr. Irhan Ibrahim Abu Hashim

A-Basic Information

1	**Faculty**	**Pharmacy**
2	**Program Title:**	**Quality Control Diploma**
3	**Program Type:**	**Single**
4	**Department (s):**	**Department of Pharmaceutics**
5	**Final award:**	**Quality Control Diploma**
6	**Coordinator:**	**Dr. Elham Abdelmonem El-said**
7	**External Evaluator(s):**	
8	**Date of Program Specification Approval:**	***Department council: 15/5/2022***

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 pharmaceutics.

1.1 Gain the different concepts and regulations of quality assurance and good manufacturing practice.

1.2 Gain information about stability calculations.

1.3 Recognize the details of quality principles, quality parameters and Good Manufacturing Practice.

1.4 Recognize the details of stability reaction kinetics and forms of instability of different dosage forms.

1.5 Know the main concepts of qualification and validation.

1.6 Obtain highly qualified pharmacist who will have a high and good experience, knowledge and skills to work in all field of pharmacy practice.

1.7 Obtain highly qualified pharmacist who will have a high and good experience, knowledge and skills to work in all fields of pharmacy practice regarding quality control testing and optimum storage conditions of different pharmaceutical products.

2-Intended Learning Outcomes (ILOs)

A. Knowledge and Understanding:

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

A1.	Identify the basic stability concept, different forms of instability and optimum storage conditions of different dosage forms.
A2.	Identify the basic concepts of Electrochemistry and Separation techniques.
A3.	Discuss stability reaction kinetics, Arrhenius equation.

A4.	Recognize half-life and shelf life of the tested formulations (stability kinetics study) and interpretation of kinetic data via different spectrometric methods.
A5.	Illustrate the different quality control tests of different dosage forms including quality control of drugs and microbiological quality control of non-sterile preparations.
A6.	Identify the general principles and objectives of quality assurance and cosmetic analysis of nutraceuticals.
A7.	Identify the key parts of good manufacturing practice.
A8.	Recall the good manufacturing practice regulations for each element of pharmaceutical products.
A9.	Recognize quality control management.
A10.	Recognize the requirements and of different good manufacturing practices including sampling, qualification, validation, documentation, packaging, labeling and inspection.

B. Intellectual Skills

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

B1.	Differentiate the different types of degradation reactions.
B2.	Verify the different quality control tests of the different dosage forms and microbiological quality control of non-sterile preparations.
B3.	Determine the half-life and shelf life of dosage forms and their pharmaceutical stability.
B4.	Decide the kinetic order describing the degradation reaction and assess the rate of reactions and the different factors affecting this rate.
B5.	Interpret the importance of quality assurance and good manufacturing practice.
B6.	Specify the requirements of each good manufacturing practice element.
B7.	Select tests for assurance of finished products.
B8.	Determine the best method for packaging
B9.	Adapt good manufacturing practice (GMP) guidelines in pharmaceutical technology.
B10.	Adapt the different electrochemical, spectrophotometric assay methods and separation techniques.

C. Professional and Practical Skills

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

C1.	Perform the different quality testing methods.
C2.	Apply the equations describing the different reaction orders.
C3.	Analyze the obtained results of the different quality testing methods.
C4.	Employ the optimum storage condition and packaging.
C5.	Apply the quality parameters.

C6.	Implement the quality variation.
C7.	Utilize the different good manufacturing practices in the production of pharmaceutical dosage forms, validation, and quality control.

D. General and Transferable Skills

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

D1.	Communicate clearly by verbal and written means.
D2.	Use information technology tools such as computer program, online database, software, and other IT to get information and analyze the obtained research data.
D3.	Practice self- assessment and learning needed for continuous professional development.
D4.	Use different available information resources relevant to pharmaceutics.
D5.	Demonstrate critical thinking, problem-solving and decision-making capabilities.
D6.	Solve and Deal with obstacles and problems.
D7.	Work effectively in a team and offer expertise and advice to others
D8.	Show creativity and time management abilities.
D9.	Retrieve and evaluate scientific work, literature, and research data.

3-Academic Reference Standards (ARS):

Approved by both the department and faculty councils.
Department Council Approval Date: *15/5/2022*
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
1. **Knowledge and Understanding**	**1.1**	A1, A3, A5, A6
	1.2	A5, A7, A8, A9, A10
	1.3	A1, A4, A10
	1.4	A10
	1.5	A10
	1.6	A9
	1.7	A2, A4
2. **Intellectual Skills**	**2.1**	B1, B2, B4
	2.2	B7, B8, B9, B10
	2.3	B3
	2.4	B7
	2.5	B3

3. **Professional and Practical Skills**	**3.1**	C1, C3, C6
	3.2	C2, C3
	3.3	C4, C5, C7
	3.4	C7
	3.5	C1
	3.6	C3
	3.7	C1
	3.8	C7
	3.9	C4, C5, C6
4. **General and Transferable Skills**	**4.1**	D1, D7, D8
	4.2	D2, D4, D5, D6
	4.3	D4, D9
	4.4	D3, D5, D8
	4.5	D3
	4.6	D7, D8

4-Curriculum Structure and Contents

4A. Program duration: 1 Year

4B. Program structure:

a- The program consists of 24 credit hours of study divided over two semesters. A graduation project is included with 2 credit hours.

b- All courses possess the code number [100], According to Faculty By-Law.

c- A scientific graduation project of 2 credit hours represents a main component of the program. It is achieved in a subject assigned by the academic supervisor, endorsed by the department council, the committee of graduate studies & research and the faculty council.

4C. Program Components

1- Courses according to the By-law

Code number	Name of the course	Type	Credit Hours	Semester
(PAD-101)	***Spectrometry***	Compulsory	2	Fall
(PAD -102)	***Quality control of drugs***	Compulsory	2	Fall
(PAD -103)	***Stability of pharmaceutical dosage forms***	Compulsory	2	Fall
(PAD -104)	***Microbiological quality control***	Compulsory	2	Fall
(PAD -105)	***Separation technique***	Compulsory	2	Spring

(PAD -106)	*Electrochemistry*	Compulsory	2	Spring
(PAD -107)	*Quality assurance*	Compulsory	2	Spring
(PAD -108)	*Food, Nutraceuticals and cosmetics analysis*	Compulsory	2	Spring
Total (Courses)	10		22	
	Graduation project		2	
Total			24	

2- Achievement of Program Intended Learning Outcomes via the courses

Course	C.H/ week	Program ILOs (by No.)			
		K.U*	IS**	P.P.S***	G.T.S****
First Semester - *(8 C.H.)*					
Spectrometry (PAD-101)	2	A4	B10	C3	D1, D2, D3, D5, D6, D7, D8
Quality control of drugs (PAD-102)	2	A5, A6, A9	B2, B5, B7	C1, C3, C5, C6	D1, D2, D3, D5, D6, D7, D8
Stability of pharmaceutical dosage forms (PAD-103)	2	A1, A3, A4	B1, B3, B4	C2, C4	D1, D2, D3, D4, D5, D6, D7, D8
Microbiological quality control (PAD-104)	2	A5	B2	C1, C3, C6	D1, D2, D3, D5, D6, D7, D8
Total	8				
SECOND SEMESTER - *(8 C.H.)*					
Separation technique (PAD-105)	2	A2	B10	C3	D1, D2, D3, D5, D6, D7, D8
Electrochemistry (PAD-106)	2	A2	B10	C3	D1, D2, D3, D5, D6, D7, D8

Quality assurance (PAD-107)	**2**	A3, A6, A7, A8, A9, A10	B5, B6, B7, B8, B9	C1, C3, C5, C6, C7	D1, D2, D3, D5, D6, D7, D8
Food, Nutraceuticals and cosmetics analysis (PAD-108)	**2**	A6	B10	C7	D1, D2, D3, D5, D6, D7, D8
Total	**8**				
Graduation project	**2**	A1, A3, A4, A5, A6, A7, A8, A9, A10	B1, B2, B3, B4, B5, B6, B7, B8, B9	C1, C2, C3, C4, C5, C6, C7	D1, D2, D3, D4, D5, D6, D7, D8, A9
Total	**24**				

* ***K**nowledge and **U**nderstanding*
** ***I**ntellectual **S**kills*
*** ***P**rofessional and **P**ractical **S**kills*
**** ***G**eneral and **T**ransferable **S**kills*

Code	Course title	K.U*										IS**									
		A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
(PAD-101)	*Spectrometry*				√																√
(PAD -102)	*Quality control of drugs*					√	√			√			√			√		√			
(PAD -103)	*Stability of pharmaceutical dosage forms*	√		√	√							√		√	√						
(PAD -104)	*Microbiological quality control*					√							√								
(PAD -105)	*Separation technique*		√																		√
(PAD -106)	*Electrochemistry*		√																		√
(PAD -107)	*Quality assurance*			√			√	√	√	√	√					√	√	√	√	√	
(PAD -108)	*Food, Nutraceuticals and cosmetics analysis (E)*						√														√
	Graduation project	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	

* ***K**nowledge and **U**nderstanding.*
** ***I**ntellectual **S**kills*
E ***Elective Course***

Code	Course title	P.P.S***							G.T.S****								
		C1	C2	C3	C4	C5	C6	C7	D1	D2	D3	D4	D5	D6	D7	D8	D9
(PAD-101)	*Spectrometry*			√					√	√	√		√	√	√	√	
(PAD -102)	*Quality control of drugs*	√		√		√	√		√	√	√		√	√	√	√	
(PAD -103)	*Stability of pharmaceutical dosage forms*		√		√				√	√	√	√	√	√	√	√	
(PAD -104)	*Microbiological quality control*	√		√			√		√	√	√		√	√	√	√	
(PAD -105)	*Separation technique*			√					√	√	√		√	√	√	√	
(PAD -106)	*Electrochemistry*			√					√	√	√		√	√	√	√	
(PAD -107)	*Quality assurance*	√		√		√	√	√	√	√	√		√	√	√	√	
(PAD -108)	*Food, Nutraceuticals and cosmetics analysis (E)*							√	√	√	√		√	√	√	√	
	Graduation project	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

*** ***P**rofessional and **P**ractical **S**kills*
**** ***G**eneral and **T**ransferable **S**kills*
E ***Elective Course***

6- Student Assessment Methods

6.1- Written exam.	To assess Knowledge and Understanding and Intellectual Skills
6.2- Oral exam.	To assess Knowledge and Understanding, Intellectual Skills and General and transferable Skills
6.3- Practical exam	Knowledge and Understanding, Intellectual Skills, Professional and practical Skills & General and Transferable Skills
6.4- Graduation project (Written exam).	Knowledge and Understanding, Intellectual Skills, Professional and practical Skills & General and Transferable Skills
6.5- Graduation project (Presentation and discussion)	Knowledge and Understanding, Intellectual Skills, Professional and practical Skills & General and Transferable Skills

7- Program Admission Requirements

7.1- The candidate should hold a bachelor's 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 student has to pass the assigned courses included the graduation project for complete fulfilment of the diploma degree.

8.3- The faculty council should cancel the student enrollment if he does not gain the diploma degree in 3 years.

8.4- 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 Search:

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.

10- Graduation project

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

11- Evaluation of program

Evaluator	Method	Sample
Internal evaluator	Program evaluation Courses evaluation	Program report Courses report
External evaluator	Program evaluation Courses evaluation	Program report Courses report
Stakeholders	Questionnaires	To be Attached
Postgraduates	Questionnaires	To be Attached
Self-evaluation	Matrices	To be Attached
Supervisor and defence committee of graduation project	Evaluation Sheet	Evaluation sheet of staff members of committee

Signature:

Course Coordinator	Head of Department	Date*
Dr. Elham Abdelmonem El-said	Prof. Dr. Irhan Ibrahim Abu Hashim	15/5/2022

Annex 1

Attach courses and thesis specifications.

Dept. of Pharmaceutics.	Course Specification	Quality control Diploma

Quality control Diploma

Quality Assurance Course Specification

Academic year: 2021/2022

توصيف مقرر **تأكيد الجودة** **Quality Assurance**	**البرنامج** **دبلوم رقابة الجودة والتحليل الدوائى**
منسق المقرر **د.أميرة محسن مطاوع**	**رئيس القسم** **أ د. ارهان ابراهيم أبوهاشم**

General

University	Mansoura
Faculty	Pharmacy
Department offering the course	Pharmaceutics
Department supervising the course	Pharmaceutics
Program on which the course is given	Quality Control Diploma Program
Academic Level	Postgraduate
Academic year	2021/2022 - second semester
Date of course specification approval	15/5/2022

A.Basic Information : Course data :

Course Title	Quality Assurance
Course Code	PAD-107
Prerequisite	------
Teaching Hours: Lecture	2 عدد الساعات الزمنية
Practical:	- عدد الساعات الزمنية
Total Credit Hours	2

B. Professional Information

1- Overall Aims of Course:

1- Gain the different concepts and regulations of quality assurance and good manufacturing practice.

2- Recognize the details of quality principles, quality parameters and Good Manufacturing Practice.

3- Know the main concepts of qualification and validation.

4- Obtain highly qualified pharmacist who will have a high and good experience, knowledge and skills to work in all field of pharmacy practice.

2- Intended Learning Outcomes (ILOs)

2.1. *Knowledge and Understanding*

After completion of the course, graduates will be able to

(A6)	a1	Identify the general principles and objectives of quality assurance and good manufacturing practice
(A7)	a2	Identify the key parts of good manufacturing practice.
(A8)	a3	Recall the good manufacturing practice regulations for each element of pharmaceutical products.
(A9)	a4	Recognize quality control management

(A10)	a5	Recognize the requirements and of different good manufacturing practices including sampling, qualification, validation, documentation, packaging, labeling and inspection.

2.2. Intellectual Skills

After completion of the course, graduates will be able to

(B5)	b1	Interpret the importance of quality assurance and good manufacturing practice.
(B6)	b2	Specify the requirements of each good manufacturing practice element.
(B7)	b3	Select tests for assurance of finished products.
(B8)	b4	Determine the best method for packaging
(B9)	b5	Adapt good manufacturing practice (GMP) guidelines in pharmaceutical technology.

2.3. Professional and Practical Skills

After completion of the course, graduates will be able to

(C5)	c1	Apply the quality parameters.
(C6)	c2	implement the quality variation
(C7)	c3	Utilize the different good manufacturing practices in the production of pharmaceutical dosage forms, validation, and quality control.

2.4. General and Transferable Skills

After completion of the course, graduates will be able to

(D4)	d1	Use different available information resources relevant to pharmaceutics
(D5)	d2	Present data clearly in oral and written
(D6)	d3	Identify and solve problems encountered in the GMP violation and the product recall
(D7)	d4	Work effectively in a team and independently.

3. Course Contents

Week No.	Lecture Topics	Hours
1	Introduction about Quality Assurance and Good Manufacturing Practice	2
2	Personnel as a key part of GMP	2
3	Buildings and facilities as a key part of GMP	2

4	Equipment as a key part of GMP	2
5	Materials as a key part of GMP	2
6	Packaging and Labeling Control	2
7	Documentation	2
8	Qualification and validation	2
9	Self-inspection	2
10	Sampling	2
Total: 10 weeks		**20**

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

Week	Topics	Course ILOs			
		K.U*	IS**	P.P.S***	G.T.S****
1	Introduction about Quality Assurance and Good Manufacturing Practice	a1	b1	c1	d2
2	Personnel as a key part of GMP	a2	b2	c1, c2	d3
3	Buildings and facilities as a key part of GMP	a2	b2	c1, c2	d3
4	Equipment as a key part of GMP	a2	b2	c1, c2	d3
5	Materials as a key part of GMP	a2	b2	c1, c2	d3
6	Packaging and Labeling Control	a5	b4	c3	d1
7	Documentation	a3, a5	b1, b5	c1	d4
8	Qualification and validation	a4, a5	b3	c3	d1
9	Self-inspection	a5	b5	c2	d3,d4
10	Sampling	a5	b3	c1	d4

** Knowledge and Understanding* ***Intellectual Skills* ****Professional and Practical Skills*
*****General and Transferable Skills*

5- Teaching and Learning Methods:

5.1	**Lectures using Power Point (PPT) presentations**
5.2	**Video-recorded lectures, uploaded to the University Portal for Online learning**
5.3	**Activities and tasks required to develop students' self-learning skills.**

6- Student Assessment:

	Assessment Methods		**Assessment Schedule**	**Weighing of Assessments**
Assessment 1	**Written Exam (Final)**	Paper exams that are corrected electronically and/or manually. To assess understanding, intellectual, professional skills	14th week	90 %
Assessment 2	**Oral Exam**	To assess understanding, intellectual skills, General and Transferable skills	14th week	10 %
Total				100 %

7- List of References

	Reference	**Type**
1.	British Pharmacopoeia, Vol., I, 1st Ed., The Stationery Office, London, U. K., (2010).	Essential Book **(Text Books)**
2.	Quality Assurance Of Pharmaceuticals: a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. – 2nd ed. By World Health Organization (2007)	Essential Book **(Text Books)**
3.	Pharmaceutical quality assurance by Nagori B.P. & et. Al, Leading publisher (2017).	Essential Book **(Text Books)**
4	Pharmaceutical Manufacturing Handbook: Regulations and Quality by Shayne Cox Gad (2008)	Essential Book **(Text Books)**
5	Pharmaceutical Manufacturing Handbook: Regulations And Quality by Shayne Cox Gad, Ph.D., D.A.B.T. Gad Consulting Services Cary, Wiley Intescience, (2008)	Recommended Books
6	Quality Systems Implementation In Pharmaceutical Industry, University Of Mauritius Journal, 436-457, Volume 15 (2009)	Recommended Books

7	http://www.sciencedirect.com http://www.google.com, http://www.pubmed.com	Website

8- Facilities required for teaching and learning

-Class room	**Data show- Computers, Internet.**
- Library	**supplied by recent scientific books**
Others	

9. Signature

Course Coordinator	Head of Department	Date
Dr. **Amira Mohsen Motawea**	**Prof Dr.** **Irhan Ibrahim Abu Hashim**	15/5/2022

* Date of Dept. Council Approval

Mansoura University
Faculty of Pharmacy
Postgraduate Studies
Quality Control and drug analysis
Diploma Program
Stability of pharmaceutical dosage forms
Course Specification
2021/2022

Dept. of *Pharmaceutics*	Course Specification	Quality Control and Drug Analysis Diploma

Quality Control and Drug Analysis Diploma

Stability of Pharmaceutical Dosage Forms

Course Specification

Academic year: 2021/2022

البرنامج	توصيف مقرر
دبلوم رقابة الجودة والتحليل الدوائى	**ثبات المستحضرات الصيدلية**

رئيس القسم	منسق المقرر
أ.د.إرهان إبراهيم أبو هاشم	**ا. م.د. الهام عبد المنعم السعيد**

General

University	Mansoura
Faculty	Pharmacy
Department offering the course	Pharmaceutics
Department supervising the course	Pharmaceutics
Program on which the course is given	Quality Control and Drug Analysis Diploma
Academic Level	Postgraduate
Academic year	2021/2022 - First semester
Date of course specification approval	15/5/2022

A: Basic Information : Course data

Course Title	Stability of pharmaceutical dosage forms
Course Code	PTD-A104
Prerequisite	.....
Teaching Hours/week : Lecture	2
Practical:	1
Total Credit Hours	3

B. Professional Information

1- Course Aims:

After completion of this course, the student will be able to:

1. Gain information about stability calculations.

2. Recognize the details of stability reaction kinetics and forms of instability of different dosage forms.

3. Obtain highly qualified pharmacist who will have a high and good experience, knowledge and skills to work in all fields of pharmacy practice regarding quality control testing and optimum storage conditions of different pharmaceutical products.

2- Intended Learning Outcomes (ILOs)

a. *Knowledge and Understanding*

After completion of the course, graduates will be able

A1	a1	Identify the different forms of instability and optimum storage conditions of different dosage forms.
A3	a2	Discuss stability reaction kinetics and Arrhenius equation
A4	a3	Recognize half-life and shelf life of the tested formulations (stability kinetics study) and interpretation of kinetic data.
A5	a4	Illustrate the different quality control tests of different dosage forms

b. Intellectual Skills

After completion of the course, graduates will be able to

B1	b1	Differentiate the different types of degradation reactions.
B2	b2	Verify the different quality control tests of the different dosage forms
B3	b3	Determine the half-life and shelf life of dosage forms.
B4	b4	Decide the kinetic order describing the degradation reaction and assess the rate of reactions and the different factors affecting this rate.

c. Professional and Practical Skills

After completion of the course, graduates will be able to

C1	c1	Perform the different quality testing methods.
C2	c2	Apply the equations describing the different reaction orders.
C3	c3	Analyze the obtained results of the different quality testing methods.
C4	C4	Employ the optimum storage condition and packaging

d. General and Transferable Skills

After completion of the course, graduates will be able to

D2	d1	Use information technology tools to retrieve information
D6	d2	Identify and solve problems
D1	d3	Present data clearly in oral and written

3. Course Contents

Week No.	Lecture Topics	Hours
1	Introduction about stability definition and importance as well as zero and first order kinetics	2
2	Second order, pseudo zero and first order kinetics as well as the methods of the order type	2
3	Determination of expiration date by accelerated stability study and Arrhenius equation	2
4	Quality control testing of emulsion	2
5	Quality control testing of suspension	2
6	Quality control testing of ointment, cream and gel	2
7	Different forms of degradation of dosage forms (instability).	2
8	Quality control testing of tablets and capsules	2
9	Optimum storage conditions of different dosage forms.	2
10	Self-Learning (Tutorial seminars presented by the students)	2
Total 10 weeks		20
Week No.	**Practical / Tutorial topics**	**hours**
1	Zero order and first order kinetics	2
2	Second order kinetics	2

3	Arrhenius equation	2
4	Quality control of tablets and capsules (Weight uniformity of tablets and capsules and tablet friability)	2
5	Quality control of tablets (Uniformity of tablet diameter and thickness and hardness test.	2
6	Disintegration and dissolution test	2
7	Quality control of suppository	2
8	Quality control of suppository	2
9	Calibration curve construction and order determination	2
10	Quality control equipment	2
Total 10 weeks		20

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

Week	Topics	Course ILOs			
		K.U*	IS**	P.P.S***	G.T.S****
1	Introduction about stability definition and importance as well as zero and first order kinetics	a2, a3	b3,b4	c2	d1,d2
2	Second order, pseudo zero and first order kinetics as well as the methods of the order type	a2, a3	b3,b4	c2	d1,d2
3	Determination of expiration date by accelerated stability study and Arrhenius equation	a2, a3	b3,b4	c2, c4	d2
4	Quality control testing of emulsion	a4	b2	c1, c3	d1,d3
5	Quality control testing of suspension	a4	b2	c1, c3	d1,d3
6	Quality control testing of ointment, cream and gel	a4	b2	c1, c3	d1,d3

7	Different forms of degradation of dosage forms (instability).	a1	b1	c4	d3
8	Quality control testing of tablets and capsules	a4	b2	c1, c3	d2,d3
9	Optimum storage conditions of different dosage forms.	a1	b1	c4	d3
10	Self-Learning (Tutorial seminars presented by the students)	a3	b1	c3	d3

** Knowledge and Understanding* ***Intellectual Skills* ****Professional and Practical Skills* *****General and Transferable Skills*

5- Teaching and Learning Methods:

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	Internet search and Research Assignments to design Formative Assignments

6- Student Assessment:

	Assessment Methods		**Assessment Schedule**	**Weighing of Assessments**
Assessment 1	**Written Exam (Final)**	Paper exams that are corrected electronically and/or manually. To assess understanding, intellectual, professional skills	At the end of semester	70
Assessment 2	**Tutorial / or Practical** assignments **and Semester work**	Assignments prepared by students and sent to the supervisor electronically for evaluation. To assess professional skills	Weak 11th	20
Assessment 3	**Oral Exam**	To assess understanding, intellectual skills, General and Transferable skills	At the end of semester	10
				100 %

7- List of References

	Reference	Type
1.	1- British Pharmacopoeia, Vol., I, 1st Ed., The Stationery Office, London, U. K., (2010). 2- Martindale, The Complete Drug Reference, 35th Ed., Sweetman, S. C., ed., The Pharmaceutical Press, London, U. K., (2007).	Essential Book **(Text Books)**
2.	1- "Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems" 8th Ed., Wolters Kluwer, Lippincott Williams and Wilkins, Philadelphia, (2005). 2- The science of dosage form design " The English language book society and Churchill Livingstone (2002). 3- "Remington's: The science and practice of pharmacy" 21st Ed., Gennaro, A. R., ed., Mack publishing C., Lippincott Williams and Wilkins, Philadelphia, (2006). 4- QUALITY, Pharmaceutical Engineering Series, Kate McCormick, Butterworth-Heinemann, London, (2002).	Recommended books.
3.	http://www.sciencedirect.com, http://www.google.com, http://www.pubmed.com	websites

8- Facilities required for teaching and learning

Class room	**Data show- Computers, Internet.**

9-Signature

Course Coordinator	Head of Department	Date
Ass.Prof. Dr. Elham Abdelmonem El Said Mohamed	Prof. Dr. Irhan Abu Hashim	15/5/2022