University : Mansoura University

Faculty : Faculty of Pharmacy

Department :

1- Course data :-

Code:	PT518					
Course title:	Industrial Pharmacy(2) & GMP					
Level:	Five					
Program Title:	• pharmaceutical sciences					
Specialization:	Major					
Teaching Hours:	**Theoretical:**	1	**Tutorial:**		**Practical:**	1

2- Course aims :-

1. Know the unit operation and unit processes.
2. Understand the different details of quality principles, quality parameters and Good Manufacturing Practice Elements (GMP).
3. Understand the different theories and principles of some unit operations (size analysis, size separation, size reduction, size enlargement, mixing and emulsification).
4. Know quality control tests of some dosage forms.

3- Intended learning outcomes of course (ILO'S) :-

a- Knowledge and understanding

1. [a6] Recall the principles of various instruments and techniques including manufacturing, packaging, labeling and storing processes in pharmaceutical industry.
2. [a8] Distinguish appropriate good manufacturing practice (GMP) and Quality Control (QC) criteria to aseptic and sterile production facilities and other pharmaceutical industry.

3. [a24] Identify the principles of quality assurance (QA) in education and of quality assurance of pharmaceutical processes and products.
4. [a2] Define the physical, chemical and microscopical properties of various substances used in preparation of medicines and the properties of different pharmaceutical dosage forms.
5. [a21] Summarize the approval process of newly introduced pharmaceutical products.

6. **b- Intellectual skills**

1. [b2] Recommend good manufacturing practice (GMP), good laboratory practice (GLP), good clinical practice (GCP) and good safety practice (GSP) guidelines in pharmaceutical technology, pharmaceutical research and pharmacy practice.
2. [b5] Design appropriate methods for isolation, synthesis, purification, identification and standardization of various chemicals and pharmaceutical compounds.

3. **c- Professional and practical skills**

1. [c3] Employ proper and safe dispersing, labeling and storing of medicines and pharmaceutical preparation.
2. [c8] Manage pharmaceutical instruments and equipment safely and efficiently and solve commonly encountered problems in pharmaceutical manufacturing processes.
3. [c4] Apply appropriate methods for extraction, isolation, synthesis, purification, identification and standardization of active substances from different origins.
4. [c14] Apply different qualitative and quantitative analytical, chemical, microscopical, and biological methods for identification, quality control (QC) and assay of raw materials as well as pharmaceutical preparations.

5. **d- General and transferable skills**

1. [d11] Plan strategies to fulfill workplace pharmaceutical needs.
2. [d3] Interact effectively in team working.
3. [d8] Present information clearly in written, electronic and oral forms.

4. [d9] Promote critical thinking, problem-solving, decision-making, and time managing capabilities.

4- Course contents :-

No	Topics	Week
1	Particle size analysis	1
2	Particle size analysis	2
3	Particle size separation	3
4	Mixing	4
5	Mixing	5
6	Emulsification & homogenization	6
7	Mid-term	7
8	Particle size reduction	8
9	Particle size reduction	9
10	Particle size enlargement	10
11	GMP	11
12	GMP	12
13	GMP	13
14	Final written & oral	15
15	Practical Topics	

5- Teaching and learning methods :-

S	Method	Knowledge and understanding	Intellectual skills	Professional skills	General skills
1	Lectures using white board and data show.	a6,a8,a24	b2	c3,c8	d11
2	Assignment	a6,a8,a24	b2	c3,c8	d11
3	Discussion session	a6,a8,a24	b2	c3,c8	d11

6- Teaching and learning methods of disables :-

1. non

7- Student assessment :-

a- Student assessment methods

No	Assessment Method	Knowledge	Intellectual	Professional	General

		and understanding	skills	skills	skills
1	Written exam	a6,a8,a24,a2,a21	b2,b5	c3,c8,c4,c14	d11,d3,d8,d9
2	Oral	a6,a8,a24,a2,a21	b2,b5	c3,c8,c4,c14	d11,d3,d8,d9
3	Quizzes	a6,a8,a24	b2	c3,c8	d11

b- Assessment schedule

No	Method	Week
1	Assessment 1	7
2	Assessment 2	13
3	Assessment 3	15
4	Assessment 4	15

c- Weighting of assessments

No	Method	Weight
1	Mid-term examination	10
2	Practical examination	25
3	Final-term examination	50
4	Oral examination	15
Total		100%

8- List of references

S	Item	Type
1	The theory and practice of industrial pharmacy 2nd Ed., lea & Febiger, Philadelphia, (2002).	Books
2	Handbook of Pharmaceutical Manufacturing Formulations 2nd Ed.,, Sarfaraz K. Niazi (2009)	Books
3	QUALITY, Pharmaceutical Engineering Series, Kate McCormick, Butterworth-Heinemann, London, (2002).	Books
4	http://www.pharmaceuticaltechnology.com	Web sites
5	http://www.sciencedirect.com	Web sites
6	http://www.pubmed.com	Web sites
7	http://www.google.com	Web sites

9- Matrix of knowledge and skills of the course

S	Course contents	Knowledge and	Intellectual skills	Professional skills	General skills

		understanding			
1	Particle size analysis	a24,a2,a21	b5	c4	d11,d8
2	Particle size analysis	a24,a2,a21	b5	c4	d11,d8
3	Particle size separation	a24,a2,a21	b5	c4	d11,d8
4	Mixing	a24,a2,a21	b5	c4	d11,d8
5	Mixing	a24,a2,a21	b5	c4	d11,d8
6	Emulsification & homogenization	a24,a2,a21	b5	c4	d11,d8
7	Mid-term	a24,a2,a21	b5	c4	d11,d8
8	Particle size reduction	a24,a2,a21	b5	c4	d11,d8
9	Particle size reduction	a24,a2,a21	b5	c4	d11,d8
10	Particle size enlargement	a24,a2,a21	b5	c4	d11,d8
11	GMP	a6,a8,a24,a21	b2	c8,c14	d11,d3,d9
12	GMP	a6,a8,a24,a21	b2	c8,c14	d11,d3,d9
13	GMP	a6,a8,a24,a21	b2	c8,c14	d11,d3,d9
14	Final written & oral	a6,a8,a24,a2,a21	b2,b5	c3,c8,c4,c14	d11,d3,d8,d9
15	Practical Topics	a6,a2	b5	c4,c14	d11,d3

Course Coordinator(s): -

Amira Mohsen Mohammed Motawea

Head of department: -

Osama abdelAzeem Soliman