Academic year 2016/2017

Course Specifications

University	Beni-Suef
Faculty	Pharmacy
Dept.	**Pharmaceutics and Industrial Pharmacy**

1-Course Info.

Programme(s) on which the course is given: Pharmaceutical Sciences

Course Name and code No.: Industrial Pharmacy 1 Code: 112

Academic year/ Level: 5th year, First term, ~~2017~~2016-~~2018~~2017

Credit hours: Lecture (2) hour + Practical (1) hour

2- Overall Aim of the Course:

By the end of this course the student should be aware with the basics of good manufacturing practice (GMP), pharmaceutical quality assurance (QA), ~~,~~ and quality control (QC). In addition to ~~and~~ the importance of documentation, pharmaceutical process validation and packaging of pharmaceutical products~~in the manufacturing of pharmaceutical products~~.

Through the knowledge and skills gained in the course, the student will be able to participate ~~work~~ in pharmaceutical facilities and quality control laboratories.

3-Intended Learning Outcomes of the course (ILOs)

a. Knowledge and understanding

After completing this course, the student should be able to:

a1. Define different terms of Good Manufacturing Practice, Good laboratory practice, Quality Assurance and Validation aspects for drug manufacturing.

a2. Identify the different materials used in pharmaceutical packaging.

a3. Enumerate different techniques of sterilization.

a4. Discuss the importance of documentation in drug manufacturing.

a5. Select materials for plant construction.

a6. Describe the safety measures in factories.

b. Professional and Practical Skills

After completing this course, the student should be able to:

b1- Diagram the flow charts of processing of different sterile products.

b2- Solve problems of dimension and units.

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b3- Use the humidity chart to obtain the different humidity parameters.

b4- Compare between different methods used in measuring of the flow properties of powders and granules.

c. Intellectual Skills

After completing this course, the student should be able to:

c1- Determine the mixing efficiency of a powder mixture.

c2- Trace the movement of personnel, raw materials, packaging materials on the lay-out of sterile rea.

3

General and Transferable Skills

After completing this course, the student should be able to:

1- Demonstrate self-learning skills.

2- Use IT to search on certain selective subjects.

Course Contents

Topics	No. of hours	
	Tutorial / Practical	Lecture
Good Manufacturing Practice		4
Pharmaceutical packaging		6
Design of sterile manufacturing facility		4
Pharmaceutical Process Validation		2
Documentation		2
Environmental Consideration		2
Materials for plant construction		2
Safety measures		2
Flow properties of powders and granules	3	
Units and dimensions	3	
Humidity	1	
Layout of sterile area	2	
Flow chart of the sterile pharmaceutical products	3	
Total	12	24

1			
2	~~Pharmaceutical packaging Part 1~~		~~Dr Adel Ahmed~~
3	~~Pharmaceutical packaging Part 2~~		~~Dr Adel Ahmed~~
4	~~Pharmaceutical packaging Part 3~~		~~Dr Adel Ahmed~~

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~~5~~	~~DESIGN OF STERILE MANUFACTURING FACILITY Part 1~~	~~Quiz 1~~	~~Dr Adel Ahmed~~
~~6~~	~~DESIGN OF STERILE MANUFACTURING FACILITY Part 2~~		~~Dr Adel Ahmed~~
~~7~~	~~GMP~~		~~Dr Amira Hosny~~
~~8~~	~~GMP~~	~~Quiz 2~~	~~Dr Amira Hosny~~
~~9~~	~~MATERIALS FOR PLANT CONSTRUCTION Part 1~~		~~Dr Amira Hosny~~
~~10~~	~~MATERIALS FOR PLANT CONSTRUCTION Part 2~~		~~Dr Amira Hosny~~
~~11~~	~~Environmental Consideration~~		~~Dr Essam Essa~~
~~12~~	~~Pharmaceutical Process Validation~~		~~Dr Amira Essa~~
~~13~~	~~Documentation~~		~~Dr Amira Essa~~
~~14~~		~~Practical exams~~	

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5- Teaching and learning Methods

5.1. Lectures

5.2. Practical laboratory work

~~5.3. Tutorial classes~~

5.~~4~~3. Research in library and web.

6- Student Assessment Methods

a-Methods:

Quizzes

Practical exam

Final Written exam

Oral exam

b- Assessment Schedule

Assessment ~~methods~~item	Week
Quiz 1	3th week
Quiz 2	~~5~~th-6th week
Final practical exam	~~11~~th-12th week
Final written exam	~~12~~th-13th week
Oral exam	

- Weighting of Assessment Marks

Quizzes: 10 %

Practical exam: 23.33 %

Final Written exam: 53.33 %

Oral exam: 13.33 %

8-List of References

a. Notes:

The department note

. Mandatory Books

United States Pharmacopoeia, The United States Pharmacopeial Convention, Inc., Rockville, MD, U.S.A., 31st ed., 2008

. Suggested Books

- **Good Manufacturing Practices for Pharmaceuticals**, by Joseph D. Nally, Volume 169, Sixth dition, Informa healthcare, New York London

- **Good Pharmaceutical Manufacturing Practice, Rationale and Compliance**. by John Sharp dited by CRC press.

- **Good Design Practices for GMP Pharmaceutical Facilities.** by Andrew A. Signore IPS afayette Hill, Pennsylvania, U.S.A. Terry Jacobs Jacobs/Wyper Architects Philadelphia, ennsylvania, U.S.A. Published in 2005 by Taylor & Francis Group.

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- **Pharmaceutical Packaging technology**., by D.A. Dean First published 2000 by Taylor & Francis.
- **Sterile Product Facility., Design and Project Management.** By Jeffery N. Odum 2nd Edition. 004 by CRC Press LLC.
- **Validation standard operating procedures: a step-by-step guide for achieving compliance in pe pharmaceutical, medical device, and biotech industries.** By Syed Imtiaz Haider, 2nd ed. Taylor Francis Group.

~~7- Pharmaceutical Dosage Forms and Drug Delivery Systems. By Howard C. Ansel 6th dition.~~

~~harmaceutics: The science of dosage from design. By M. E. Aulton 2nd edition.~~

emington: The Science and Practice of Pharmacy. By Alfonso R. Gennaro – 20th edition

. Journals

Pharm. Sci., International

. Pharmaceutics, Drug Development and Industrial Pharmacy and

. Pharmacy Pharmacol.

he most concerned web sites are those of the FDA, ICH and WHO who contentiously issuing uidelines on the subject.

Course Coordinator:

Head of department: ……

Date: ……

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