Orientation to Pharmacy (PHT 101)

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Pharmaceutical Technology
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Title: Orientation & History of Pharmacy	**Code:** PHT 101	**Prerequisites: N/A**
Students' Level/Semester:	First year/First semester	
Credit Hours: 2 hr	**Lecture:** 2 hrs/week	**Practical:** N/A
Tutorial: N/A	**Total:** 2 hrs/week	

B. Professional Information

1. Overall Aim of Course

The course deals with a study of the scope of pharmacy, pharmacy careers, ethics, practice of community pharmacy as well as the role of pharmacists in industry, hospital, government, military and research. The course also includes pharmacy education, international and national organizations. A historical background of the pharmaceutical sciences, including different preludes of history, associated with the development of the profession of pharmacy in ancient Egypt and Arab countries is also included in this course.

2. Intended Learning Outcomes (ILOs)

By the end of this course, the student should be able to:

a- Knowledge and Understanding:

a1. Identify the scope of pharmacy and the available careers.
a2. Outline the suitable career for pharmacists.
a3. Explain the influence of pharaohs and Arab on improvement of the career.

b- Intellectual Skills:

b1. Apply the code of ethics.
b2. Choose which career the student would prefer.
b3. Practice pharmaceutical profession.

c- Professional and Practical Skills:

c1. Apply the given information on the daily requirements of patients.

d- General and Transferable Skills:

d1. Explain to public how to administer a certain dosage form.
d2. Value the importance of physician directions.
d3. Rate himself to other pharmacists.
d4. Employ suitable persons who can help to improve community.
d5. Practice how to deal with other health care team

3. Contents

Week	Topic	No. of hours	Lecture
One	Scope of pharmacy (1)	2	1
	History of pharaohs (1)		1
Two	Scope of pharmacy (2)	2	1
	History of pharaohs (2)		1
Three	Career of pharmacy (1)	2	1
	History of Coptic (1)		1
Four	Career of pharmacy (2)	2	1
	History of Coptic (2) **First Mid-Term Exam**		1
Five	Role of pharmaceutics (1)	2	1
	History of Arabs (1)		1
Six	Role of pharmaceutics (2)	2	1
	History of Arabs (2)		1
Seven	Role of pharmaceutics (3)	2	1
	History of Arabs (3)		1
Eight	**Second Mid-Term Exam.**		
Nine	Ethics of pharmacy (1)	2	1
	History of modern Egypt (1)		1
Ten	Ethics of pharmacy (2)	2	1
	History of modern Egypt (2)		1
Eleven	Pharmaceutical industry profile (1)	2	1
	History of modern Egypt (1)		1
Twelve	Pharmaceutical industry profile (2)	2	1

	History of modern Egypt (2)		1
Thirteen	Revision	2	1
			1
Total No. of Hours		**24**	**24**
Fourteen	**University Elective Final Exam**		
Fifteen	**Final Exam**		
Sixteen			

4. Teaching and Learning Methods

4.1. Data show and computer lectures.

4.2. Power point presentation.

4.3. Seminars.

5. Student Assessment Methods

5.1. Written exam to assess Knowledge, understanding, intellectual as well as professional skill.

5.2. Semester Work (Participation and Open discussions) to assess general and transferable skills.

Assessment Schedule

Assessment 1 1st Mid-Term exam Week 4

Assessment 2 Mid- Term exam Week 8

Assessment 3 Final exam Week 15/16

Assessment 4 Semester Work (Participation and open discussions) (During the semester)

Weighting of Assessments

1st Mid-Term exam	5%
2nd Mid-Term Examination	35%
Final-Term Examination	50%
Semester Work	10%
Total	**100%**

6. List of References

6.1. Course Notes

Staff lectures handouts are **uploaded to the Moodle**

6.2. Essential Books (Text Books)

- Pharmaceutical dosage from and drug delivery systems (Ansel), 9th edition, and publisher-Lippincott Williams Wilkins, 2011.

6.3. Recommended Books

- Remington: The science and practice of pharmacy, 20th ed., Lippincott Williams &Wilkins, Philadelphia, 2013.

6.4. Periodicals, Websites, ……etc

www.pubmed.com

www.rxlist.com

7. Facilities Required for Teaching and Learning

1- Computer equipped with data show
2- White board

Course Coordinator: Assoc. Prof. Dr. / Mona Ibrahim Abdel Tawab EL-Assal

Head of Department: Prof. Dr. / Hussein Ammar

Department Approval Date: September 2014

Mathematics (PHT 151)

Course Specifications

Program (s) on which the course is given: Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program: All Faculty Departments
Department offering the course: Pharmaceutical Technology Department
Academic year: 2014/2015
Approval date : September 2014

A. Basic Information

Course Title: Mathematics
Course Code: PHT 151
Prerequisites: No Prerequisite.
Students' Level/Semester: First level/ First semester
Credit hours: **2**
Actual teaching hours per week:
Lectures: 2/week **Practical:** N/A **Tutorial:** N/A **Total:** 2/week

B. Professional Information

1. Overall Aim of Course

Mathematical thinking is important for all members of modern society as a habit of mind for its use in the workplace, business and finance; and for personal making decision for pharmacist and how to do survey.

2. Intended Learning Outcomes (ILOs)

By the end of the course, students should be able to:

a- Knowledge and Understanding:

a1. Recognize different methods of solving problems.
a2. Identify how to use the matrices for solving a system of equations.

b- Intellectual Skills:

b1. Apply differentiation and integration in pharmaceutical calculations.
b2. Select appropriate method to solve a given problem.
b3. Apply different methods of calculations in pharmacy practice.
b4. Use matrices for solving a system of equations.

c- Professional and Practical Skills:

c1. Apply mathematical principles in pharmaceutical calculations.

c2. Use numeracy, calculation and statistical methods as well as information technology tools.

c3. Use Cartesian and semilog papers to plot graphs.

d- General and Transferable Skills:

d1. Use different resources for obtaining data to act as a lifelong learner.

3. Contents:

Week	Topic	No. of hours	Lecture
One	Real Numbers	**2**	**2**
Two	Linear inequalities	**2**	**2**
Three	Factorization of Algebraic Expression	**2**	**2**
Four	First Midterm Exam Solving a system of linear equation. **+ First Mid-term**	**2**	**2**
Five	Equations of Straight Lines & circle.	**2**	**2**
Six	Limits	**2**	**2**
Seven	Revision	**2**	**2**
Eight	**Second Mid-Term Exam**	**-**	**-**
Nine	Differentiation	**2**	**2**
Ten	Integration	**2**	**2**
Eleven	Functions & graphs	**2**	**2**
Twelve	Matrices and application	**2**	**2**
Thirteen	Matrices and application	**2**	**2**
Total no. of hours		**24**	**24**
Fourteen	Final exams of Faculty		
Fifteen			
Sixteen			

4. Teaching and Learning Methods

- **4.1.** Lectures
- **4.2.** Problem solving
- **4.3.** Oral discussions

5. Student Assessment Methods

- **5.1.** Written exams to assess overall knowledge and intellectual skills.
- **5.2.** Behavior & Participation to assess general and transferrable skills
- **5.3.** Assignments to assess professional skills

Assessment Schedule

Assessment 1 First Mid-term	week 4
Assessment 2 Second Midterm exam	week 8.
Assessment 3 Final exam	week 16
Assessment 4 Assignments	Every lecture
Assessment 5 Behavior & Participation	Every lecture

Weighting of Assessments

1st Mid-term Exam	10%
2nd Mid-Term Exam	30%
Final Exam	40%
Behavior & Participation	10%
Assignment	10%
Total	**100%**

6. List of References

6.1. Course notes

Handout of lectures' presentation given by instructor to students

6.2. Essential Book (Text Books)

- Ernest F. Haeussler, Jr. & others, **introductory life and Mathematical Analysis for Business Economics and the Social sciences** (United States of America: Pearson prentice hall, edition 11, 2006).

6.3. Recommended Books

None

6.4. Periodicals, Websites,….etc

www.Wikepedia.com

7. **Facilities Required for Teaching and Learning**
   Data show.
   Board & Marker.

Course Coordinator Dr. Zeinab Tawfik

Head of Department Prof. Dr. Hussein Ammar

Department Approval Date September 2014

Physical Pharmacy (PHT 111)

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Department of Pharmaceutical Technology
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Physical Pharmacy **Course Code:** PHT 111

Prerequisites: General and Physical Chemistry (PHC 101)

Students' Level/Semester: First Level / Second Semester

Credit hours: 3 (2+1)

Actual teaching hours per week:

Lectures: 2/week **Practical:** 2/week **Tutorial:** N/A **Total:** 4/week

B. Professional Information

1. Overall Aim of Course

This course aims to provide the student with good knowledge to study some physical pharmacy principles including state of matter and phase equilibria, solubility, rheology, surface phenomena and surfactants, the colligative properties emphasizing on those applicable to various topics of pharmaceutics and focusing on the theories behind phenomena needed for dosage form design.

2. Intended Learning Outcomes (ILOs)

By the end of this course student should be able to:

a- Knowledge and Understanding:

a1. Define state of matter and phase equilibria.
a2. Recognize the problems and solutions accompanying phase equilibria
a3. Recognize the useful pharmaceutical applications of different Phase diagrams.
a4. Identify the different principles about solution and solubility.
a5. State the different factors affecting the drug solubility
a6. Name the different factors affecting the drug dissolution rate
a7. Recognize surface activity.
a8. Explore the types of surfactants and their use.
a9. Describe different types of rheological behaviors in pharmaceutical dosage forms.
a10. Identify the importance of rheology in preparing effective dosage forms.
a11. Outline the colligative properties of solutions.

b- Intellectual Skills:

b1. Analyze problems regarding the phase equilibria, solution and solubility, surface phenomina, rheology, colligative properties.
b2. Select the suitable additives to adjust the solubility of a drug in a certain dosage form.
b3. Apply the learned data to enhance the solubility of drugs.
b4. Predict solubility of drugs to formulate the proper dosage forms.
b5. Select proper surfactants in pharmaceutical industry.
b6. Determination the viscosity of given substance in order to draw the different rheograms.
b7. Apply the knowledge gained of colligative properties in pharmacy particularly in the preparation of isotonic solutions.
b8. Apply the fundamentals of adsorption and its significant in pharmaceutical applications.

c- Professional and Practical Skills:

c1. Analyze experimental work adopting physical pharmacy background.
c2. Examine graphically the different data and results.
c3. Interpret the results obtained from experimental designs.
c4. Determine the rheological properties of different dosage forms.
c5. Choose the best additives to increase drug solubility.
c6. Design a successful physically stable liquid dosage form.

d- General and Transferable Skills:

d1. Interpret the results obtained due to problems relevant to physical principles.
d2. Interact efficiently with others.
d3. Work effectively in a team.

3. Contents

Teaching Week	Topic	No. of hours	Lecture	Practical
One	-Rheology - State of matter	**4**	**2**	
	- Density of liquids			**2**
Two	-Rheology - Solution & solubility.	**4**	**2**	
	- Critical micelle concentration			**2**
Three	-Rheology - Solution & solubility.	**4**	**2**	
	-Rheology			**2**
Four	- Solution & solubility.	**4**	**2**	

	- Surface and interfacial tension.			
	Hydrophilic-lipophilic balance **1st Midterm Exam**			**2**
Five	-	**4**	**2**	
	- Effect of electrolytes on the solubility of benzoic acid			**2**
Six	- Surface and interfacial tension - Phase equilibrium and phase rule	**4**	**2**	
	The effect of pH on the solubility of weak electrolytes.			**2**
Seven	- Surface and interfacial tension - Phase equilibrium and phase rule	**4**	**2**	
	- Distribution of solutes between two immiscible liquids.			**2**
Eight	**2nd Midterm Exam**			
Nine	- Surface and interfacial tension - Phase equilibrium and phase rule	**4**	**2**	
	Revision			**2**
Ten	- Collegative properties - Solution & solubility	**4**	**2**	
	Practical exam & Quiz			**2**
Eleven	- Solution & solubility	**4**	**2**	
	Practical exam & Quiz			**2**
Twelve	- Solution & solubility	**2**	**2**	
Thirteen	**Revision**	**2**	**2**	
Total no. of hours		**44**	**24**	**20**
Fourteen	**University Elective Final Exams**			
Fifteen	**Final Exams**			
Sixteen				

4. Teaching and Learning Methods

4.1. Lectures.
4.2. Practical.
4.3. Group Discussion
4.4. Interactive Lecture (Students' Response System through Clickers).
4.5. Data Analysis.

5. Student Assessment Methods

5.1. Discussions in lectures and labs to assess mainly knowledge and understanding.

5.2. Written exams to assess mainly knowledge and understanding as well as intellectual skills.

5.3. Practical work to assess mainly professional and practical skills.

5.4. Semester Work (lab performance) to assess mainly knowledge and understanding of the practical part, intellectual skills as well as professional and practical skills

5.5. Oral exam to assess all skills including transferable skills.

5.6. Quiz to assess understanding of the practical part.

Assessment Schedule

Assessment 1… Written Exams	Week: (4, 8, 15/16)
Assessment 2 … Practical Exam	Week: (10-11)
Assessment 3… Quiz	Week: (10-11)
Semester Work (Lab performance)	each lab
Oral exam	Week (15/16)

Weighting of Assessments

1st Mid-Term Examination		5 %
2nd Mid-Term Examination		15 %
Final-Term Examination		30 %
Oral Examination		10 %
Semester Work (Lab performance)		10 %
Practical		30 %
Practical Examination	25 %	
Quiz	5 %	
Total		**100 %**

6. List of References

6.1. Course Notes

Staff lectures handouts are **uploaded to the Moodle**.
lab manual **is given to each student**.

6.2. Essential Books (Text Books)

Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, Patrick J

Sinko, 6th ed. Lippincott Williams& Wilkins, Philadelphia, 2010. **(Given to each student)**

Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, 20th ed., Lippincott Williams & Wilkins, Philadelphia, 2000. **(Available at the library)**

6.3. Recommended Books

Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Michael E Aulton, 3rd ed., Elsevier Health Sciences, UK, 2007.

6.4. Periodicals, Websites, ……etc

http://www.wikipedia.org/

7. Facilities Required for Teaching and Learning

- Classroom clickers (student response systems).
- Computer equipped with projector
- White board.
- Different laboratory equipment (viscometer, stalagmometer, pycnometer, water bathes and glass ware …..etc).

Course Coordinator: Prof. Dr. Seham A. Elkheshen

Head of Department: Prof. Dr. Hussein O. Ammar

Department Approval Date: September 2014

Introduction to Pharmaceutics (PHT 212)

Course Specifications

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Pharmaceutical Technology department
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Introduction to pharmaceutics **Course Code:** PHT 212

Prerequisites: ----------

Credit Hours: 1 hr.

Students' Level/Semester: Second year/ third semester

Actual teaching hours per week: 1 hr.

Lecture: 1 hr./week **Practical** N/A **Tutorial:** N/A **Total:** 1 hr./week

B. Professional Information

1. Overall Aim of Course

The course gives the student an introduction to dosage forms including liquid, semisolid, solid, aerosol and sterile dosage forms. It also gives an idea about types of prescriptions as well as their parts and how to compound a prescription. Factors affecting dosage, dosage calculation, pediatric and geriatric doses as well as incompatibilities and methods of their correction are also included in this course.

2. Intended Learning Outcomes (ILOs)

By the end of this course the student should be able to:

a. Knowledge and Understanding:

a1. Define different types of prescription

a2. Define different types of incompatibilities and methods of correction.

a3. Recognize dosage forms.

a4. Recognize the difference between various Pharmaceutical dosage forms.

a5. Classify the factors affecting dosage forms.

b. Intellectual Skills:

b1. Deduce the differences between different dosage forms.

b2. Write proper dosing based on knowing factors that affect dosage.
b3. Detect possible incompatibilities in prescriptions.
b4. Calculate doses for pediatrics and geriatrics.
b5. Select suitable dosage forms for patients especially pediatrics and geriatrics.

c-Professional and Practical Skills:

c1. Solve problems arising due to incompatibilities.
c2. Solve problems encountered in prescriptions.

d-General and Transferable Skills:

d1. Communicate effectively with others.
d2. Inform physician and patients with possible prescription incompatibilities.
d3. Use different resources to update his scientific information.

3. Contents

Teaching Weeks	Topic	No. of hours	Lecture
One	The prescription	1	1
Two	Liquid dosage form (coarse dispersion)	1	1
Three	Solid dosage form (powder & granules)	1	1
Four	Solid dosage form (capsules)	1	1
	First Midterm Exam		

Five	Solid dosage form (tablets)	1	1
Six	Molded dosage forms (suppository)	1	1
Seven	Semisolid dosage form (ointment)	1	1
Eight	**Second Midterm Exam**		
Nine	Semisolid dosage form (cream - gel)	1	1
Ten	Sterile dosage form (parenteral, ophthalmic) + **Handling of Assignments**	1	1
Eleven	Incompatibility (Physical, chemical , therapeutic))	1	1
Twelve	Dosage calculation	1	1
Thirteen	Revision	1	1
Total No. of hours		12	12
Fourteen	**University Elective Final Exam**		
Fifteen	**Final Exams of Faculty**		
Sixteen			

4. Teaching and Learning Methods

4.1. lectures.
4.2. Power point presentations.
4.3. Seminars.
4.4. Movies

5. Student Assessment Methods

5.1. Semester Work (Participation) to assess understanding well as general and transferable skills.
5.2. Assignment to assess professional and practical skills.
5.3. Written exams to assess knowledge and understanding as well as intellectual skills.

Assessment Schedule

Assessment 1 First midterm Exam Week 4
Assessment 2 Second midterm Exam Week 8
Assessment 3 Handling of Assignment Week 10
Assessment 4 Final exam Week 15/16
Assessment 5 Semester Work (Participation) During the semester

Weighting of Assessment

1st Mid-Term Examination	5	%
2nd Mid-Term Examination	35	%
Final-Term Examination	50	%
Semester Work	5	%
Assignment	5	%
Total	**100**	**%**

6. List of References

6.1. Course Notes
Staff lecture handouts are **uploaded to the Moodle.**

6.2. Essential Books (Text Books)

- Ansel's pharmaceutical dosage forms for drug delivery system, nine edition, and publisher-Lippincott Williams Wilkins, 2011.

6.3. Recommended Books

- Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, 20th ed., Lippincott Williams & Wilkins, Philadelphia, 2013.

6.4. Periodicals, Websites, ……etc

www.pubmed.com

www.rxlist.com

7. Facilities Required for Teaching and Learning

White board, computer equipped with a data show

Course Coordinator: Assoc. prof. Dr. Mona Ibrahim Abd El Tawab

Head of Department: Prof. Hussein Ammar

Department Approval Date September 2014

FUTURE UNIVERSITY IN EGYPT
FACULTY OF PHARMACEUTICAL SCIENCES AND PHARMACEUTICAL INDUSTRIES

Course Specifications

Pharmaceutics 1 (PHT 213)

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Pharmaceutical Technology Department
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Pharmaceutics 1 **Course Code:** PHT 213

Prerequisites: Introduction to Pharmaceutics (PHT 212)

Students' Level/Semester: Second Level/ Fourth Semester

Credit hours: **4 (3+1)**

Actual teaching hours per week:

Lectures: 3/week **Practical:** 2/week **Tutorial:** N/A **Total:** 5/week

B. Professional Information

1. Overall Aim of Course

By the end of the course, the student should gain various aspects of pharmaceutical sciences of development, formulation and quality control of liquid dosage forms including solutions, colloids, suspensions, emulsions. In addition, the student will learn the required pharmaceutical calculations for second year pharmacy students.

2. Intended Learning Outcomes (ILOs)

By the end of the course, the student should be able to:

a- Knowledge and Understanding:

a1. List types of solvents and methods of preparation of solutions.
a2. Enumerate different types of colloidal sol, methods of preparations and purification.
a3. Define electric double layer of interface.
a4. Name different theories used in formulation of suspensions
a5. State different types of emulsions as well as surfactants used.
a6. Define different methods of extraction.
a7. Distinguish Roman numbers and different measuring systems.
a8. Recognize methods of dose calculation.

b- Intellectual Skills:

b1. Distinguish the different types of pharmaceutical solutions and methods of preparation.
b2. Differentiate different types of colloids and their application and their purification.
b3. Recognize different types of suspensions.

b4. Calculate the quantity needed of ingredients to fulfill a given prescription.
b5. Solve mathematical problems concerning roman number, metric system, avoirdupois, Apothecaries weighing theories and allegation.

c- Professional and Practical Skills:

c1. Formulate aqueous, hydro-alcoholic and effervescent solutions.
c2. Prepare suspensions using different types of suspending agents.
c3. Choose the appropriate surfactant in preparation of emulsions.
c4. Write the appropriate label for a dispensed formulation.

d- General and Transferable Skills:

d1. Communicate with others about the usage of different dosage forms.

d2. Work effectively within a team.

d3. Interact positively in class.

3. Contents

Teaching Weeks	Topic	No. of hours	Lecture	Practical
One	• Roman Numerals, Metric System • Common systems • • Suspensions: Definition, routes of administration, advantages and disadvantages.	**5**	**2** **1**	
	• Ammonium Chloride mixture • Iron Ammonium Citrate mixture			**2**
Two	• Pharmaceutical solutions and their types • Classification of solutions, Advantages and disadvantages • Types of solvents used in formulations • - Methods of preparations of solutions , types of water, Methods of water purification • Suspension: Theory of sedimentation (Stock's law and	**5**	**2** **1**	

	factors affecting the rate of sedimentation (viscosity-particle size-density difference between medium and particle),			
	• Potion Reviere Magnesium citrate mixture			**2**
Three	• Pharmaceutical Solutions (cont.) aqueous solution, water purification ، • Pharm calculations • -Dose calculations and related calculations • • Suspension: Factors affecting the rate of sedimentation (viscosity-particle size-density difference between medium and particle), Advantage and disadvantage of high medium viscosity	5	**2** **1**	
	• Elixir • Salting out • Tincture Myrrh			**2 (1)**
Four	• Pharm solutions. Aqueous solution gargles, mouthwash, douches, enema, otic and nasal drops. • Suspensions (cont.) • -Sedimentation parameters (sediment volume – degree of flocculation-their comparison) • Types of suspensions (flocculated and deflocculated and comparison) **+ First Midterm Exam**	**4**	**2** **1**	
	• Aromatic Water			**2**

	• Mist Alba			
Five	• Pharmaceutical Solutions (cont.) -aromatic waters, preparation of aromatic waters - Suspensions (Cont.) • Interfacial property of suspended particles (flocculated – deflocculated) Rheology of flocculated and deflocculated suspension.	**5**	**2** **1**	
	• Heavy MgO suspension Calamine lotion			**2**
Six	• Pharmaceutical Solutions (cont.) • -Viscid solutions (syrups, jelly, mucilage, honey • Pharmaceutical calculations: Allegation • Suspensions (Cont.) • agents-flocculating agents-suspending agents) •	**5**	**2** **1**	
	• Mouthwash • Decoction infusion			**2**
Seven	• Pharmaceutical Solutions (cont.) • -Non aqueous solutions (elixir, liniment, collodion, glycerites, oleovitamis) • Pharm calculations (allegation) • • Emulsions - • Types of emulsions (o/w, w/o, multiple, micro emulsions) • - Tests of differentiation between o/w and w/o emulsions	**4**	**2** **1**	
	• Castor Oil emulsion • Liquid Paraffin emulsion			**2**
Eight	**Second Midterm exam**			

Nine	• Pharmaceutical Solutions (cont.) • - Non aqueous solutions (cont) • Emulsions (cont.) • - How emulsifying agent stabilize emulsion (theory of emulsification) • Emulsifying agent types	**5**	**2** **1**	
	Revision			**2**
Ten	• Pharmaceutical Solutions (cont.) • Extractives - Colloids -Definition • -Types of colloids: (lyophilic, lyophobic, association), Method of preparation of lyophobic colloid (dispersion methods, electric arc, condensation methods). Association colloid structure, CMC. Purification of colloids (dialysis, electro-dialysis- ultra filtration) • Emulsions (cont.) - Emulsifying agent types. -Types of synthetic emulsifiers - What are spans and tweens and their water loving characters	**5**	**2** **1**	
	Final Practical Exam			**2**
Eleven	• Pharmaceutical Solutions (cont.) -Additives (cont) • Colloids (cont.) Stability of colloid ,(coagulation – coacervation), Gold number, Hofmeister series • Properties of colloids: • Optical properties (Tyndall effect-ultramicroscopy - electron microscopy- light scattering) • Emulsions (Cont.) • - Stability of emulsion [physical	**3**	**2** **1**	

	(creaming –coalescence] and chemical (incompatibility of emulgent- oxidation-microorganisms-temperature) - Stability testing of emulsion – method of preparation of emulsion.			
				2
Twelve	• Pharmaceutical Solutions (cont.) -Additives (cont) • Colloids (cont.) Properties of colloids: 2- Kinetic properties (Brownian motion- sedimentation – diffusion-osmotic pressure-viscosity) 3- Electrical properties of interface (source of surface charge – electric double layer double layer- zeta potential –Nernst potential)	**3**	**2** **1**	
Thirteen	**Revision**	**3**	**3**	
Total No. of hours		**54**	**36**	**18**
Fourteen	**Final Exams of Faculty**			
Fifteen				
Sixteen				

4. Teaching and Learning Methods

4.1. power point presentations

4.2. laboratory sessions

5. Student Assessment Methods

5.1. Quiz to assess efficient study.

5.2. Written exams to assess knowledge and understanding as well as intellectual skills.

5.3. Practical exams to assess professional and practical skills.

5.4. Oral exams to assess all types of skills and mainly general and transferrable skills

5.5. Semester Work (Participation) to assess all types of skills.

Assessment Schedule

Assessment 1 1 st Midterm Exam……Week 4.
Assessment 2 2nd Midterm Exam…… …Week 8.
Assessment 3 …Practical exam+ Practical sheet .. Week 10
Assessment 4 …Final Written Exam ……..…Week 15/16
Assessment 5 …Oral Exam……Week 15/16
Assessment 6…..Semester Work…….During the semester

Weighting of Assessments

1st Mid-Term Examination		5 %
2nd Mid-Term Examination		15 %
Final-Term Examination		30 %
Oral Examination		10 %
Practical		30%
-Practical Examination	25 %	
- Practical sheet	5%	
Semester Work		10 %
Total		**100 %**

6. List of References

6.1. Course Notes

Handouts, Lab manual

6.2. Essential Books (Text Books)

- Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V Allen, Nicholas G Popovich, Howard C Ansel, 10th ed., Lippincott Williams & Wilkins**,** Philadelphia, 2014.

- Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, 22nd ed., Lippincott Williams & Wilkins, Philadelphia, 2012.

6.3. Recommended Books

- Martin's: physical pharmacy and pharmaceutical science, sixth edition and publisher-Lippincott Williams Wilkins, 2006.

6.4. Periodicals, Websites, ……etc

http://www.Pubmed.com/

7. Facilities Required for Teaching and Learning

Computers equipped with projectors.
Smart boards and markers.
Facilities for practical: glassware, balances, water baths, etc……

Course Coordinator
Professor Dr. Dalia Samuel

Head of Department
Professor Dr. Hussein Ammar

Department Approval Date: September 2014

FUTURE UNIVERSITY IN EGYPT
FACULTY OF PHARMACEUTICAL SCIENCES AND PHARMACEUTICAL INDUSTRIES

Course Specifications

Pharmaceutics II (PHT 314)

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Department of Pharmaceutical Technology
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Pharmaceutics II **Course Code:** PHT 314

Prerequisites: Introduction to Pharmaceutics (PHT 212)

Students' Level/Semester: Third Level/ Fifth Semester

Credit hours: 4 (3+1)

Actual teaching hours per week:

Lectures: 3hrs/week **Practical:** 2hrs/week **Tutorial:** N/A **Total:** 5hrs/week

B. Professional Information

1. Overall Aim of Course

This course comprises study of solid, semisolid as well as molded semisolid dosage forms. This course aims to familiarize the students with solid pharmaceutical dosage forms, and to employ the different unit operations in the preparation and manufacturing of these dosage forms including powder, granules, coated and uncoated tablets, hard gelatin capsules and soft gelatin capsules. In addition, this course describes some aspects of dermal delivery for topical disorders and also for systemic problems as ointments, creams, gels, pastes and transdermal patches. Molded semisolid preparations comprising different types of suppositories are also included. Furthermore, the student will acquire the knowledge of modified release drug delivery systems and methods of achieving them.

2. Intended Learning Outcomes (ILOs)

By the end of the course, student should be able to:

a- Knowledge and Understanding:

a.1. List types, advantages and disadvantages of solid dosage forms
a.2. Identify types of pharmaceutical powders and granules
a.3. Recall the skin structure, composition of trans dermal patches and semi solid dosage forms
a.4. Differentiate between the various types of tablet dosage forms
a.5. List categories of inert ingredients, with examples, which are employed in the manufacture of compressed tablets and capsules

a.6. Identify problems encountered during manufacturing of solid dosage forms
a.7. Distinguish the methods of manufacturing of solid dosage forms
a.8. Define different types of ointment bases creams and suppositories
a.9. Outline the methods of preparation of ointments, creams and suppositories
a.10. State quality standards and USP compendial requirements for tablets
a.11. Describe the modified release dosage forms

b- Intellectual Skills:

b1. Compare advantages and disadvantages of the various types of dosage forms to choose rationally the formulations suitable for preparation of solid, semisolid as well as molded semisolid dosage forms.
b2. Apply logical thinking to solve problems related to solid, semisolid as well as molded semisolid dosage forms manufacturing.
b3. Deduce the methods of achieving a successful solid dosage form formulation.
b 4. Predict the pathway of permeates through the skin

c- Professional and Practical Skills:

c1. Compound medicines effectively and safely.
c2. Select dosage forms based on understanding etiology of diseases
c3. Apply techniques used in operating pharmaceutical equipment and instruments.
c4. Formulate different types of dosage forms.
c5. Solve problems in different theoretical and practical situations
c6. Estimate the role of excipients in the formulation of tablets, capsules, suppositories, ointments, gels.

d- General and Transferable Skills:

d1. Communicate with patients for the selection of different dosage forms

d2. Work effectively in a team

d3. Interact positively in class

3. Contents

Teaching Weeks	Topic	No. of hours	Lecture	Practical
One	solid dosage forms, pharmaceutical powder and granules - Skin Structure and types of dermatologicals	**5**	**3**	
	Preparation of ointments (zinc			**2**

	oxide and sulfur ointments)			
Two	Tablet dosage forms (tablet press machines, tablet additives, granulation) -Semisolid preparations: ointments	**5**	**3**	
	Preparation of cold creams			**2**
Three	- Tablet (Wet granulation (reciprocating granulator, fluid bed, and spray drier- properties of tablet additives) - Semisolid preparations: ointments (cont) , cerates and creams	**5**	**3**	
	Preparation of vanishing and shaving creams.			**2**
Four	- Problems of tablet manufacture - Semisolid preparations: pastes , poultices and gels	**5**	**3**	
	Preparation of pastes **First Midterm Exam**			**2**
Five	- Tablets coating - Suppositories	**5**	**3**	
	Preparation of cacao butter based suppository			**2**
Six	-Evaluation of tablets - Factors affecting rectal absorption	**5**	**3**	
	Preparation of glycerol-gelatin based suppository			**2**
Seven	- Hard Gelatin Capsules - Suppositories quality control	**5**	**3**	
	Preparation of soap glycerin based suppository			**2**
Eight	**Second Midterm Exam**			
Nine	- Soft gelatin capsules Bioadhesives	**5**	**3**	

	Preparation of macrogol based suppository			**2**
Ten	- Modified release dosage forms (Delayed release products) Transdermal drug delivery	**5**	**3**	
	Preparation of effervescence granules			**2**
Eleven	- Modified release dosage forms (Extended release products) Transdermal patches design	**5**	**3**	
	Revision			**2**
Twelve	- Modified release dosage forms (repeat action) Transdermal enhancers	**5**	**3**	**2**
	Final Practical Exam + Quiz			
Thirteen	Modified release dosage forms (target release) Microparticles in drug delivery	**3**	**3**	
Fourteen	**Final Exams of Faculty**			
Fifteen				
Sixteen				

4. Teaching and Learning Methods

4.1. Data show and computers in lectures.
4.2. Demonstration videos.
4.2. Group discussion
4.3. Self-learning
4.3. Practical work.

5. Student Assessment Methods

5.1. Practical exam: to assess professional and practical skills.

5.2. Quiz : to assess theoretical background of the practical and intellectual skills.
5.3. Written exams: to assess knowledge and understanding as well as Intellectual skills.
5.4. Oral exam: to assess all types of skills including general and transferrable skills.
5.5. Semester Work (Lab performnce) to assess all types of skills.

Assessment Schedule

Assessment 1 …. Written exam Week: (4, 8, 15/16)
Assessment 2 … Practical exam Week: (12)
Assessment 3… Quiz Week: (12)
Assessment 4…Oral exam Week (15/16)
Assessment 5….Semester Work (Lab performance) Each lab

Weighting of Assessments

First Mid-Term Exam	5 %
Second Mid-Term Exam	15 %
Final Exam	30 %
Oral Exam	10 %
Practical Exam + Quiz	30 %
Semester Work (lab performance)	10 %
Total	100 **%**

6. List of References

6.1 Course Notes

Handouts and lab manual.

6.2 Essential Books (Text Books)

- Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V Allen, Nicholas G Popovich, Howard C Ansel, 10th ed., Lippincott Williams & Wilkins**,** Philadelphia, 2014.
- Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Michael E Aulton, 3rd ed., Elsevier Health Sciences, UK, 2007.
- Controlled Release in Oral Drug Delivery, Clive G Wilson, Patrick J Crowley, Springer, New York, Dordrecht, Heidelberg, London, 2011.

6.3 Recommended Books

- Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, Patrick J Sinko, 6th ed. Lippincott Williams & Wilkins**,** Philadelphia, 2011.

- Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, 22nd ed., Lippincott Williams & Wilkins, Philadelphia, 2012.

6.4 Periodicals, Websites, ……etc

http://www.Pubmed.com/

7 Facilities Required for Teaching and Learning

1. Computer equipped with projector
2. White board.
3. Different laboratory equipment, suppositories molds, hot plates, water bathes, porcelain dishes.

Course Coordinator Prof. Dalia Samuel

Head of Department Prof. Dr. Hussein O. Ammar

Department Approval Date: : September 2014

Pharmaceutics III PHT 315

Course Specifications

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty departments
Department offering the course:	Pharmaceutical Technology Department
Academic year:	2014/2015
Date of specification approval:	September 2014

A. Basic Information

Course Title: Pharmaceutics 3 **Course Code:** PHT 315
Prerequisites: Pharmaceutics I (PHT 213)
Students' Level/Semester: Third Level/ Sixth Semester
Credit Hours: 3 **(2+1)**
Actual teaching hours per week:
Lecture: 2 hr/week **Practical:** 2 hr/week **Tutorial:** N/A **Total:** 4/week

B. Professional Information

1. Overall Aim of Course

The course deals with sterile dosage forms. The course is designed to provide the student with adequate knowledge on sterile dosage forms including parenteral and ophthalmic as well as sterilization processes. The course deals also with aerosols and inhalations dosage forms, also including radio pharmaceutics and their applications.

2. Intended Learning Outcomes (ILOs)

By the end of the course, the student should be able to:

a- Knowledge and Understanding:

a1. Define the different types of parenteral dosage forms and their route of administration and their preparation techniques.
a2. List methods of parenteral sterilization, validation and quality control.
a3. Discuss methods of preparation, uses of small and large volume parenteral dosage form.
a4. Indicate other sterile dosage form as pellets and irrigation solutions.
a5. Identify different types of ophthalmic dosage forms, drops, gels, ointments and inserts.
a6. Outline the role of mucoadhesive ocular dosage form in improving drug bioavailability.

a7. Outline the use of nanoparticle drug delivery systems as ophthalmic dosage forms.
a8. Describe radiopharmaceuticals techniques of decay and application.
a9. Identify methods of solubilization.

b- Intellectual Skills:

b1. Select the proper parenteral dosage form to be given to patient.
b2. Detect the proper sterilization technique for a given dosage form.
b3. Differentiate between different types of ophthalmic dosage forms.
b4. Solve problems encountered in the preparation of ophthalmic dosage forms.
b5. Indicate different types of radioisotopes and techniques of decay.
b6. Choose the appropriate drug salts, buffers and tonicity adjusters.
b7. Assess problems relevant to isotonic and buffer adjustments.
b8. Calculate the quantities of chemicals needed to formulate a given prescription of parenteral dosage forms.
b9. Solve mathematical problems concerning isotonicity adjustment, milliequivalent weight calculations, millimoles and milliosmoles.

c- Professional and Practical Skills:

c1. Prepare isotonic electrolyte solutions and infusion fluids.
c2. Solve the problems encountered during the formulation
c3. Solve buffer arising problems.
c4. Prepare buffer solutions.

d- General and Transferable Skills:

d1. Defines ideas based on scientific debates.
d2. Work effectively in a team.
d3. Communicate effectively with others.

3. Contents

Teaching Weeks	Topic	No. of hours	Lecture	Practical
One	• Parenteral preparations & route of administration • Ophthalmic Dosage Forms:	2	1	

	- Human eye - Ophthalmic drug delivery Cul-de-sac, tears volume, causes of poor bioavailability, ocular drug absorption)		1	
Two	• Official types of injections & component of parenteral • Ophthalmic dosage form	4	1 1	
	• NaCl Equivalent method			2
Three	• Formulation and preparation of parenteral. • Ophthalmic dosage form	4	1 1	
	• Electrolyte solutions (milliequivalent)			2
Four	• Solvents for injection. • The rule of mucoadhesive in ophthalmic dosage form • **First Midterm Exam**	4	1 1	
	Millimoles + Milliosmole			2
Five	• Methods of sterilization • Nanoparticle dosage form	4	1 1	
	Revision			2
Six	• Validation of sterilization • Difficulty that a formulator should overcome during the development of ophthalmic suspension. • Nanoparticle dosage form	4	1 1	
	Quiz			2
Seven	• The industrial preparation of	4	1	

	parenteral products (Packaging, labeling & storage of injections) • Aerosol types – Mode of operation – propellants - containers		1	
	• Determination of Buffer capacity • Preparation of isotonic buffer			2
Eight	• **Second midterm exam**			
Nine	• Small &large volume parenteral (Replacement therapy) • Special consideration with parenteral therapy • Spray valves – Actuator – Filling operation	4	1 1	
	• Solubilization of aspirin using salting in mechanisms			2
Ten	• Other injectable products • Irrigation solution • Parenteral Quality control • Formulation and delivering of therapeutic inhalation	4	1 1	
	• Solubilization of salicylic acid through micelle formation			2
Eleven	• Definition (atomic number-mass number-isotope-isotone-isobars) • Types of radiation, types of radioactive decay. • Unit of radioactivity, exposure dose, absorbed dose, rate of decay.	4	1 1	
	• Revision lab.			2
Twelve	• Methods of measurement of radiation • Source of radioisotopes,	4	1	

	Application of radio isotopes, harmful effect of radiation. • Radioprotection		1	
	• **Practical exam**			2
Thirteen	• Revision	2	1 1	
Total		**44**	**24**	**20**
Fourteen	• **University Elective Final Exam**			
Fifteen	• **Final Exams of Faculty**			
Sixteen				

4. Teaching and Learning Methods

4.1. Power point presentations
4.2. Videos.
4.3. Quiz
4.4. Laboratory sessions

5. Student Assessment Methods

5.1. Quiz to assess efficient study.
5.2. Semester Work (Open talks) to assess knowledge and understanding.
5.3. Written exams to assess knowledge and understanding as well as intellectual skills.
5.4. Assignment to assess all types of skills.
5.5. Practical exams to assess professional and practical skills.
5.6. Oral exams to assess all skills mainly general and transferrable skills.

Assessment Schedule

Assessment 1 First midterm exam Week.4.
Assessment 2 Quiz Week 6.
Assessment 3...Second midterm exam Week 8.
Assessment 4 assignment Week 10
Assessment 5 Practical exam Week 12 .
Assessment 6 Final exam Week 15/16
Assessment 7 Oral exam Week 15/16
Assessment 8 Semester work (Open discussions) During the semester

Weighting of Assessments

1st Mid-Term Examination	5	%
2nd Mid-Term Examination	15	%
Final-Term Examination	30	%
Oral Examination	10	%
Practical Examination	30	%
{Practical Exam.5% - Quiz 20% - Assignment 5%}		
Semester Work	10	%
Total	**100**	**%**

6. List of References

6.1. Course Notes

Handouts **uploaded on Moodle.**
Lab Manual.

6.2. Essential Books (Text Books)

- Ansel's pharmaceutical dosage forms for drug delivery system, nine edition, and publisher-Lippincott Williams Wilkins, 2011.
- Remington: The science and practice of pharmacy, 2013.

6.3. Recommended Books

- Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, Patrick J Sinko, 6th ed. Lippincott Williams& Wilkins, 2011.

6.4. Periodicals, Websites, ……etc

www.pubmed.com
www.rxlist.com

7. Facilities Required for Teaching and Learning

Computers equipped with projectors and white boards.
Facilities for practical: glassware, pipettes, Bruits, electric balance, etc…..

Course Coordinator: Assoc. Prof. Dr. Mona Abdel Tawab El-Assal

Head of Department: Prof. Dr. Hussein Ammar

Department Approval Date: September 2014

Reaction Kinetics & Drug Stability (PHT 421)

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Department of Pharmaceutical Technology
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Reaction Kinetics & Drug Stability **Course Code:** PHT 421

Prerequisites: Mathematics (PHT 151) and Physical Pharmacy (PHT 111)

Students' Level/Semester: Fourth Level / Seventh Semester

Credit hours: 3 (2+1)

Actual teaching hours per week:

Lectures: 2/week **Practical:** 2/week **Tutorial:** N/A **Total:** 4/week

B. Professional Information

1. Overall Aim of Course

The course provides the student with the knowledge of the degradation rate of drugs and the methods to determine the order of degradation reaction. Also, this course provides the student with the ability to predict the degradation pathways of a drug design, a stabilization protocol and predict a product shelf-life. The course also familiarizes the students with the official regulations for the conduction of stability studies.

2. Intended Learning Outcomes (ILOs)

By the end of this course student should be able to:

a- Knowledge and Understanding:

a1. Recognize the theoretical background regarding the order of reaction.

a2. Describe the difference between the different reaction orders regarding the dependence of the reaction rate on the initial concentration.

a3. Describe the difference between the different orders regarding the dependence of the fractional life on the initial concentration.

a4. Recognize the different factors affecting the rate of drug degradation.

a5. Recognize the potential of the formulation factors and the storage conditions on the stability of the different dosage forms.

a6. Discuss the chemical instability problems and how to stabilize drugs against them and the methods of evaluation.

a7. Recognize problems related to drug stability.

a8. Recognize the international and the national regulation concerning the stability study of drugs in different dosage forms.

b- Intellectual Skills:

b1. Predict the effect of temperature on the drug stability and its relation to drug shelf life determination.
b2. Estimate the orbitery reduction in the shelf life upon storage under non-standard conditions.
b3. Conduct calculations necessary for establishing the expiration dates of different pharmaceutical products.
b4. Detect the possible instability problem a drug molecule might suffer based on the chemical structure of the drug.
b5. Recommend a suitable dosage form, additives, and storage conditions based of the stability problem facing the drug.
b6. Suggest suitable stabilization methods for drugs in the various dosage forms.

c- Professional and Practical Skills:

c1. Apply different methods to determine the order of the reaction.
c2. Estimate the relationship between the drug degradation rate and its storage conditions with the drug product shelf life.
c3. Apply methods to increase the product shelf-life.
c4. Establish a proper stability study to assess the instability of the drug in a dosage form and determine the proper expire date
c5. Apply relevant stability protocols for testing various pharmaceutical products.

d- General and Transferable Skills:

d1. Interpret the degradation order depending on data obtained from problems.
d2. Work in a team to develop a stability project.
d3. Interact efficiently in a team.

3. Contents

Teaching Week	Topic	No. of hours	Lecture	Practical
One	Introduction of course spec. Important Definition in reaction kinetics, kinetic expression, order of reaction, apparent or pseudo-order reactions, Zero order reaction	**4**	**2**	
	Introduction of the practical course, Laboratory safety measures			**2**

	and conduct code.			
Two	- Half life and shelf life of Zero order reactions, Suspension as apparent zero order - Drugs decomposing by hydrolysis	**4**	**2**	
	Introduction + Zero order problems			**2**
Three	- First-order reactions - Drugs decomposing by hydrolysis	**4**	**2**	
	First order problems (Therotical + Graphical Representation)			**2**
Four	- Second-order reactions - Drug decomposing by oxidation	**4**	**2**	
	Experiment 1: The hydrolysis of ethyl acetate using 1N HCl as a catalyst **1st Midterm Exam**			**2**
Five	- Complex, parallel, consecutive and reversiblereactions	**4**	**2**	
	Second order problems & miscellaneous problems			**2**
Six	- Determination of reaction order - Determination of the cause of drug decomposition	**4**	**2**	
	Experiment 3: The effect of hydrogen ion concentration on the hydrolysis of ethyl acetate			**2**
Seven	- Factors affecting the rate of reaction - Design of a stability study	**4**	**2**	
	Arrhenius problems			**2**
Eight	**2nd Midterm Exam**			
Nine	- Factors affecting the rate of reaction, effect of temperature - Design of a stability study	**4**	**2**	
	Experiment 4: The effect of temperature on the rate of acid hydrolysis of ethyl acetate			**2**
Ten	- Factors affecting the rate of reaction, effect of formulation factors - Storage condition	**4**	**2**	

	Experiment 2: Determination of the reaction rate constant of the hydrolysis of ethyl acetate in presence of an equal quantity of sodium hydroxide			**2**
Eleven	- Factors affecting the rate of reaction, effect of pH - Determination of a product shelf-life	**4**	**2**	
	Practical quiz + Practical Exam			**2**
Twelve	- Determination of a product shelf-life	**4**	**2**	
	Practical quiz + Practical Exam			**2**
Thirteen	The international, ICH Guideline, as approved by the WHO and the national (Egyptian Ministry of Health) regulation concerning conducting the stability study of drugs in different dosage forms.	**2**	**2**	
Total no. of hours		**46**	**24**	**22**
Fourteen	**University Elective Final Exams**			
Fifteen	**Final Exams of Faculty**			
Sixteen				

4. Teaching and Learning Methods

4.1. Data show and computer in lectures.
4.2. Demonstration videos.
4.3. Group discussion
4.4. Data Analysis.

5. Student Assessment Methods

5.1. Written Exam to assess knowledge and understanding as well as intellectual skills.
5.2. Practical Work to assess mainly professional and practical skills.
5.3. Quiz to assess mainly knowledge and understanding of the practical part, intellectual skills as well as professional and practical skills.

5.4. Discussion of reports prepared by students: to assess mainly their ability of self-learning and their transferable skills.

5.5. Oral exam to assess all skills including transferable skills.

5.6. Semester Work (lab performance) to assess all types of skills.

Assessment Schedule

Assessment 1… Written Exam	Week: (4, 8, 15/16)
Assessment 2 … Practical Exam	Week: (11-12)
Assessment 3… Quiz	Week: (11-12)
Assessment 4…Semester Work (Lab performance)	Each lab
Assessment 5…Oral Exam	Week; (15/16)

Weighting of Assessments

1st Mid-Term Examination		5 %
2nd Mid-Term Examination		15 %
Final-Term Examination		30 %
Oral Examination		10 %
Semester Work		10 %
Practical		30 %
Practical Quiz Exam	5%	
Assignments and reports	5%	
Practical Experiment	20 %	
Total		**100 %**

6. List of References

6.1. Course Notes

Staff lectures handouts are **uploaded to the Moodle**.

Lab manual **is given to each student**.

6.2. Essential Books (Text Books)

Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, Patrick J Sinko, 6th ed. Lippincott Williams& Wilkins, Philadelphia, 2010. **(Given to each student)**

6.3. Recommended Books

Drug Stability for Pharmaceutical Scientists, Loftsson, T., Academic Press, Oxford, UK, 2014.

Guideline: ICH Harmonised Tripartite: Stability testing of new drug substances and products. Q1A (R2), Current Step 4, 2013.

6.4. Periodicals, Websites, ……etc

http://www.wikipedia.org/

7. Facilities Required for Teaching and Learning

- Computer equipped with projector
- White board.
- Different laboratory equipment.

Course Coordinator: Prof. Dr. Seham A. Elkheshen

Head of Department: Prof. Dr. Hussein O. Ammar

Department Approval Date: September 2014

Biopharmaceutics & Pharmacokinetics (PHT 431)

Course Specifications

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All departments
Department offering the course:	Department of Pharmaceutical Technology
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Biopharmaceutics & Pharmacokinetics
Course Code: PHT 431
Prerequisites: Reaction Kinetics & Drug Stability (PHT 421)
Students' Level/Semester: Fourth Level/ Eighth Semester
Credit hours: 4 (3+1)
Actual teaching hours per week:
Lectures: 3/week **Practical:** N/A **Tutorial:** 2/week **Total:** 5/week

B. Professional Information

1. Overall Aim of Course

This course introduces the students to the concept of biopharmaceutics and pharmacokinetics. It deals with the kinetics of drug absorption, distribution and elimination as well as the effect of physicochemical properties and formulation on the rate and extent of drug absorption. The course also deals with compartmental models, volume of distribution, multiple dosing, renal, hepatic excretions and assessment of dosage regimen.

2. Intended Learning Outcomes (ILOs)

By the end of this course, the student should be able to:

a- Knowledge and Understanding:

a1. List the factors that affect drug bioavailability.

a2. Define pharmacokinetics, pharmacodynamics, compartment models, volume of distribution and total body clearance.
a3. State the factors affecting gastrointestinal absorption.
a4. Name different routes of drug administration.
a5. Outline factors affecting the dissolution rate of drugs.
a6. Identify parameters for assessment and comparison of bioavailability.
a7. Define bioequivalence of drug products.
a8. Describe factors affecting drug metabolism.
a9. Recognize pharmacokinetic principles.

b- Intellectual Skills:

b1. Estimate drug absorption
b2. Categorize transport mechanisms of drugs
b3. Predict different compartmental model systems.
b4. Plan dosage regimens for patients to accomplish a desired steady state in multiple drug administration.

c- Professional and Practical Skills:

c1. Draw curves representing relationships between time and concentration of drug in plasma following intravenous and extravascular administration.
c2. Calculate half-life and elimination rate constant following intravenous administration of different drugs.
c3. Calculate half-life, absorption rate constant and elimination rate constant following extravascular administration of different drugs.
c4. Solve problems related to renal clearance of drugs.
c5. Distinguish between pharmaceutical equivalents, pharmaceutical alternatives and therapeutic equivalents of different drug products.
c6. Design appropriate pharmaceutical dosage forms exhibiting adequate bioavailability

d- General and Transferable Skills:

d1. Recommend new dosage regimens in case of patients suffering renal impairment.

3. Contents

Teaching Weeks	Topic	No. of hours	Lecture	Practical
One	• Scope of biopharmaceutics, pharmacokinetics & principles of drug absorption. • Passive diffusion	5 hrs.	2 hrs. 1 hr.	
	• Introduction to Pharmacokinetics			2 hrs
Two	• Specialized transport mechanisms (Active transport, Facilitated diffusion) • Dissolution and drug absorption	5 hrs.	2 hrs. 1 hr.	
	• Pharmacokinetics of drugs administrated by i.v. route 1- One Compartment model in i.v. injection single dose. A- Calculation of k from plasma data			2 hrs.
Three	• Factors affecting gastrointestinal absorption (Gastric emptying time). • Drug surface area, crystal or amorphous drug form	5 hrs.	2 hrs. 1 hr.	
	• Pharmacokinetics of drugs administrated by i.v. route (Cont.) B- Calculation of k from urinary excretion data.			2 hrs.
Four	• Salts form, the state of hydration of a drug molecule. • Bioavailability and bioequivalence (Blood, serum or plasma concentration time curve)	5 hrs.	2 hrs. 1 hr.	
	• Pharmacokinetics of drugs administrated by i.v. route (Cont.)			2 hrs.

	2- Two Compartment model in i.v. injection single dose.			
	First Midterm exam			
Five	• Parameters for assessment and comparison of bioavailability (Peak height). • Parameters for assessment and comparison of bioavailability (Time of peak, Area under the serum conc. time curve).	5 hrs.	2 hrs. 1 hr.	
	• Pharmacokinetics of drugs administrated by i.v. route (Cont.) 3- I.V. administration, Multiple Dosing: A- I.V. infusion			2 hrs.
Six	• Bioequivalence of drug products (Pharmaceutical equivalents) • Bioequivalence of drug products (Pharmaceutical alternatives and therapeutic equivalents).	5 hrs.	2 hrs. 1 hr.	
	• Pharmacokinetics of drugs administrated by i.v. route (Cont.) B. I.V. multiple dose adminstration			2 hrs.
Seven	• Factors that influence bioavailability of oral drugs (Drug substance physicochemical properties, pharmaceutical ingredients). • Factors that influence bioavailability of oral drugs (Dosage form characteristics, physiological factors and patient characteristics)	5 hrs.	2 hrs. 1 hr.	
	• Pharmacokinetics of drug absorption .			2 hrs.
Eight	**Second midterm exam**			

Nine	• Routes of drug administration (Oral route) • Routes of drug administration (rectal route)	5 hrs.	2 hrs. 1 hr.	
	• Extravascular Multiple Dosing			2 hrs.
Ten	• Routes of drug administration (Parenteral route: subcutaneous injections, intramuscular injections and intravenous injections). • Ocular, aural and nasal routes, fate of drug after absorption • Epicutaneos route	5 hrs.	2 hrs. 1 hr.	
	• Bioavailability • Clearance and renal clearance.			2 hrs.
Eleven	• Drug metabolism or biotransformation • Excretion of drugs. • Pharmacokinetics principles (One-compartment model)	5 hrs.	2 hrs. 1 hr.	
	• Dissolution			2 hrs.
Twelve	• Two-compartment model, half-life. • Concept of clearance • Dosage regimen considerations (Empirical therapy) • Dosage regimen considerations (Kinetic approach).	5 hrs.	2 hrs. 1 hr.	
	• Revision			2 hrs.
Thirteen	Revision	5	3	
	Practical exam			2
Total No. of hours		**60**	**36**	**24**
Fourteen				

Fifteen	**Final exams of Faculty**		
Sixteen			

4. Teaching and Learning Methods

4.1. Lectures.
4.2. Data show.
4.3. Board and marker.
4.4. Discussion and brain storming

5. Student Assessment Methods

5.1. Written exams assess the student's understanding, comprehension, intellectual and professional skills
5.2. Practical exams assess the professional and practical skills.
5.3. Oral exams asses all types of skills and mainly the general and transferable skills.
5.4. Class work (Participation) to assess all types of skills.

Assessment Schedule

Assessment 1	First midterm exam	**Week**	4
Assessment 2	second midterm exam	**Week**	8
Assessment 3	Practical exam (Tutorial)	**Week**	13
Assessment 4	Final Exam	**Week**	15/16
Assessment 5	Oral Exam	**Week**	15/16
Assessment 6	Class Work	**(During the semester)**	

Weighing of Assessments

First Midterm Examination	5%
Second Mid-Term Examination	15%
Final-Term Examination	30%
Oral Examination	10%
Practical Examination	30%
▪ Quizzes	10 %
▪ Practical sheet exam	20%
Classwork	10%
Total	100**%**

6. List of References

6.1. Course Notes

Course handout.
Lab manual

6.2. Essential Books (Text Books)

- Ansel's Pharmaceutical dosage forms and drug delivery systems, eighth edition, and publisher-Lippincott Williams Wilkins, 2010.

6.3. Recommended Books

- Leon Shargel, Susanna Wu-Pong, Andrew B.C.Yu, " Applied Biopharmaceutics & Pharmacokinetics", sixth edition, 2012.

6.4. Periodicals, Websites, ……etc

www.Pubmed.com
www.rxlist.com
www.cspsa.com

7. Facilities Required for Teaching and Learning

7.1. Data Show.
7**.2.** White Board & Markers.
7.3. Cartesian and semilog graph copybooks.

Course Coordinator Prof. Dr. Hussein Ammar
Head of Department Prof. Dr. Hussein Ammar

Department Approval Date: September 2014

Industrial Pharmacy 1 (PHT 522)

Course Specifications

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Pharmaceutical Technology department
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Industrial Pharmacy I **Course Code:** PHT 522

Prerequisites: Phramaceutics 2 (PHT 314)

Credit Hours: 3 hr. (2+1)

Students' Level/Semester: Level 5/ Ninth semester

Actual teaching hours per week:

Lecture: 2 hr./week **Practical** 2 hrs/week **Total:** 4 hr./week

B. Professional Information

1. Overall Aim of Course

This course gives the student information about how planning for construction takes place as well as validation and maintenance of modern pharmaceutical facilities. This course helps the student to develop, design, build, validate and implement a pharmaceutical plant. The student will have an idea about the environmental considerations for the layout of industrial firms, material for plant construction and safety measurements in factories. The student will be aware of manufacturing of active pharmaceutical ingredients and packaging materials. Information about the ISO certificate is taught as well.

2. Intended Learning Outcomes (ILOs)

By the end of the course, the student will be able to:

a- Knowledge and Understanding:

a1. Identify the basis of pharmaceutical industry profile in Egypt and other countries all over the world.

a2. Recognize the basis of layout, planning facilities, mechanical utilities for pharmaceutical factory.

a3. Order the leading companies and blockbuster products in the pharmaceutical industries all over the world.

a4. Match between the employed safeties in the pharmaceutical plants.

a5. Memorize the conditions required for efficient production of the various pharmaceutical products.
a6. Mention the GMP and GLP guidelines for pharmaceutical plants.
a7. State the ISO specifications and requirements.
a8. Describe how pharmaceutical plants could prepare themselves for audits.
a9. Define the sterile area, related infrastructure and equipment.

b- Intellectual Skills:

b1. Predict the appropriate construction material for various equipment.
b2. Select appropriate safety measurements in pharmaceutical plants.
b3. Convert the laboratory units to the appropriate industrial units.
b4. Analyze the marketing data for various pharmaceutical companies.
b5. Estimate the market share and the annual growth rate percentages for the investigated companies.
b6. Categorize the available pharmaceutical plants in the Egyptian market according to type and purpose.
b7. Compare between the available packaging materials for the same pharmaceutical product.

c- Professional and Practical Skills:

c1. Use the proper industrial terms and abbreviations utilized in industrial plants.
c2. Employ proper documentation and drug filing systems as required by GMP and GLP.
c3. Sketch appropriate diagrams showing layout of industrial plants.
c4. Estimate the flowability and mixing efficiency of powder mixture.
c5. Write brief reports about the recent activities in the pharmaceutical industry field
c6. Compare between the global marketing trends (eg. merges versus divestments) in major industrial companies.
c7. Apply the requirements for ISO certification of pharmaceutical plants.
c8. Justify the reasons and possibilities for extension of an existing industrial plant (building or acquisition of another plant).
c9. Analyze the published reports of the financial and market structures of major industrial companies.

d- General and Transferable Skills:

d1. Communicate clearly by appropriate industrial terms.

d2. Use numeracy and calculation to convert laboratory units to the appropriate industrial units.
d3. Demonstrate creativity in plotting a simple layout for an industrial plant.

3. Contents

Week	Topic	No. of Hours	Lecture	Practical
One	- Pharmaceutical industrial profile.	**4**	**2**	
	- Units and dimensions. - Pharmaceutical industry-related definitions			**2**
Two	- Pharmaceutical industrial profile.	**4**	**2**	
	- Dimensions and units. - Pharmaceutical industry-related definitions			**2**
Three	- API facilities.	**4**	**2**	
	- Layout sketches of pharmaceutical industry factories. - Pharmaceutical industry-related definitions			**2**
Four	- API facilities. - First midterm exam	**4**	**2**	
	- Layout sketches of pharmaceutical industry factories. - Pharmaceutical industry-related definitions + **First Midterm Exam**			**2**
Five	- Mechanical utilities.	**4**	**2**	
	- Sketches of mechanical utilities. - Pharmaceutical industry-related definitions			**2**
Six	- Mechanical utilities.	**4**	**2**	

	- Sketches of sterile area.			**2**
Seven	- Safety measures in facilities.	**4**	**2**	
	- Estimation of the flow properties of powders and granules: I- Determination of the bulk density (gm/cm^3). II- Measurement of the flow rate.			**2**
Eight	**Second Midterm Exam**			
Nine	- Safety measures in facilities.	**4**	**2**	
	- Estimation of the flow properties of powders and granules: III- Measurement of the angle of repose. IV. Determination of the optimum glidant concentration.			**2**
Ten	- ISO principals	**4**	**2**	
	- Determination of the mixing efficiency of a powder mixture.			**2**
Eleven	- ISO 9000 and 14000 series	**4**	**2**	
	- Physicochemical testing of packaging materials.			**2**
Twelve	- GMP guidelines.	**4**	**2**	
	- Practical revision			**2**
Thirteen	- GMP and GLP basics.	**2**	**2**	
	Practical Exam			
Total no. of hours		**48**	**24**	**24**
Fourteen	**University Elective Exams**			
Fifteen	**Final exams of Faculty**			
Sixteen				

4. Teaching and Learning Methods

4.1. Power point lectures.

4.2. Practical Labs.

4.3. Internet search

5. Student Assessment Methods

5.1. Written exam to assess overall knowledge and intellectual skills.

5.2. Practical exam to assess professional and practical skills.

5.3. Practical exam quiz to assess theoretical background of the practical part.

5.4. Oral exam to assess all types of skills (mainly general and transferable skills).

5.5. Semester Work (Lab performance + Student's project) to assess all types of skills.

5.6. Practical quiz to assess knowledge of practical part.

Assessment Schedule

Assessment 1… Written exam	Week: (4, 8, 15)
Assessment 2 … Practical exam	Week: (13)
Assessment 3… Practical exam quiz	Week (13)
Assessment 4… Oral exam	Week: (15)
Lab performance	Each lab
Student's Project	During the semester

Weighting of Assessments

First Mid-Term Examination		5 %
Second Mid-Term Examination		15 %
Final-Term Examination		30 %
Oral Examination		10 %
Practical Examination		30 %
Practical exam	25%	
Practical exam quiz	5%	
Semester Work		10 %
Lab performance	5%	
Students' project	5%	
Total		**100%**

5. List of References

6.1. Course Notes

Notes on Industrial Pharmacy I, Mina Ibrahim Tadros

Lab manual: Practical Industrial Pharmacy I, Mina Ibrahim Tadros

6.2. Essential Books (Text Books)

- Aulton's Pharmaceutics: The design and manufacture of medicines, Michael Aulton

Publisher: Churchill Livingstone, 4th Edition, 2013.

- The theory and Practice of Industrial Pharmacy, Leon Lachman.

Publisher: Lea & Febiger, 4th Edition, 2009.

6.3. Recommended Books

Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard Ansel

Publisher: Lippincott Williams & Wilkins, 10th Edition, 2014.

6.4. Periodicals, Websites, ……etc

Periodicals: Journal of Drug Development and Industrial Pharmacy.

Websites: www.pubmed.com , www.Rxlist.com , www.Pharmweb.com

6. Facilities Required for Teaching and Learning

a. Personal computer equipped with a data show.

b. White board.

c. Internet searching.

d. Faculty Pharmaceutical Factory

Course Coordinator

Dr. Mina Ibrahim Tadros

Head of Department

Prof. Dr. Hussein Ammar

Department Approval Date: September 2014

Industrial Pharmacy II (PHT 523)

Course Specifications

Program (s) on which the course is given: Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program: All Faculty Departments
Department offering the course: Pharmaceutical Technology Department
Academic year: 2014/2015
Approval Date: September 2014

A. Basic Information

Course Title: Industrial Pharmacy II **Course Code:** PHT 523
Prerequisites: Pharmaceutics 2 (PHT 314)
Students' Level/Semester: Level 5/ Tenth semester
Credit hours: 3 (2+1)
Actual teaching hours per week:
Lectures: 2hr. /week **Practical:** 2hr. /week **Total:** 4hr. /week

B. Professional Information

1. Overall Aim of Course

By the completion of the course, the student will have learnt all the basic knowledge in the area of industrial unit operations (particle size reduction and particle size enlargement, powder and liquid mixing, heat transfer, evaporation, extraction, drying, etc. ….) and the specific manufacturing factors associated with the preparation and evaluation of tablets.

2. Intended Learning Outcomes (ILOs)

By the end of the course, the student will be able to:

a- Knowledge and Understanding:

a1. Describe the sequential production steps involved in the production of pharmaceutical products (raw materials, intermediates and finished marketed products).
a2. Describe the basic concepts of industrial unit operations like particle size reduction, particle size enlargement, powder and liquid mixing, heat transfer, evaporation, extraction and drying.
a3. Enumerate the environmental factors influencing the design of each unit operation.
a4. Identify the experimental variables to optimize the production operations.

a5. Select the most appropriate equipment for each unit operation.
a6. Order the unit operations involved in each process train.
a7. Define the commonly used industrial terminology.

b- Intellectual Skills:

b1. Recognize the problems emerging during the production of various products.
b2. Distinguish tablet-related problems like capping and lamination.
b3. Convert the laboratory units to their corresponding industrial units.
b4. Solve problems related to heat transfer, drying using the suitable dimensions and units.
b5. Develop the possible solutions to the problems encountered with flow ability of powders.
b6. Analyze the variables influencing the heat transfer and drying.
b7. Evaluate the extraction (solid-liquid and liquid-liquid) processes.

c- Professional and Practical Skills:

c1. Use the appropriate equipment efficiently, safely and economically.
c2. Plot suitable sketches for commonly used equipment in the pharmaceutical industry.
c3. Determine the optimum glidant concentration to improve powder flowability.
c4. Choose the best heat transfer agent for heat conduction.
c5. Prepare tablets on a large scale in a well established industrial plant.
c6. Design an appropriate experiment to measure the flowability of powders.
c7. Justify the reasons and possibilities for obtaining extra equipment to achieve a reliable comprehensive system.

d- General and Transferable Skills:

d1. Communicate clearly by appropriate industrial terms.
d2. Use numeracy and calculation to convert laboratory units to the appropriate industrial units.
d3. Demonstrate creativity in plotting industrial equipment.
d4. Use different resources to get updated with the most recent advances in industrial equipment and unit operations.

3. Contents

Week	Topic	No. of hours	Lecture	Practical
One	Particle size reduction	**4**	**2**	

	In Factory: Mixing with V-shaped & double cone blenders (study the effect of the type of mixer, mixing time and mixing RPM).			**2**
Two	Particle size reduction	**4**	**2**	
	In labs: 1. *Size reduction* (Hammer mill + Ball mill + Cutter mill). 2. *Size enlargement* (Reciprocating horizontal granulator + Perforated basket granulator).			**2**
Three	Particle size enlargement	**4**	**2**	
	In Factory: 1. Wet granulation with planetary mixer using gum / alcohol. 2. Drying of granules in ovens.			**2**
Four	Particle size enlargement. First midterm exam	**4**	**2**	
	In labs: 1. *Size enlargement* (Chilsonator). 2. *Mixing* (Tumbler mixers+ Nauta mixer + High shear mixer/granulator) + **First Midterm exam**			**2**
Five	Powder mixing	**4**	**2**	
	In Factory: 1. Tabletting of granules using a rotary Tablet press. 2. Measurement of tablet weight variation, hardness and friability			**2**

	for the prepared tablets and 2 market products (Rivo® and Adol®).			
Six	Liquid mixing	**4**	**2**	
	In labs: *Heat transfer* (Problems, Steam dryers + Steam traps + Floating head heat exchanger).			**2**
Seven	Tablet manufacturing process	**4**	**2**	
	In Factory: 1. Measurement of tablet disintegration and dissolution. 2. Preparation of a calibration curve of a model drug (paracetamol).			**2**
Eight	**Second Midterm Exam**			
Nine	Tablet coating techniques	**4**	**2**	
	In labs: *Drying* (Fluidized bed dryer + Tray dryer + Lyophilizer + Standard spray dryer).			**2**
Ten	Heat transfer	**4**	**2**	
	In Factory: 1. Assay of drug content using UV spectrophotometer. 2. Demonstration of HPLC apparatus.			**2**
Eleven	Drying	**4**	**2**	

	In labs: 1. *Evaporation* (Problems, Horizontal tube evaporator + Vertical tube evaporator + Forced circulation evaporator). 2. *Extraction* (Batch percolator + Packed column tower).			**2**
Twelve	Drying	**4**	**2**	
	Revision in factory and labs			**2**
Thirteen	Revision	**4**	**2**	
	Practical Exam			**2**
Total no. of hours		**48**	**24**	**24**
Fourteen	University Elective Exams			
Fifteen	Final exams of Faculty			
Sixteen				

4. Teaching and Learning Methods

4.1. Power point lectures.

4.2. Practical Labs.

4.3. Internet search

4.4. Projects (where students are classified into groups and each group is asked to design or simulate industrial equipment).

5. Student Assessment Methods

5.1. Written exam to assess overall knowledge and intellectual skills.

5.2. Practical exam to assess professional and practical skills.

5.3. Practical exam quiz to assess theoretical background of the practical part.

5.4. Oral exam to assess all types of skills (mainly general and transferable skills).

5.5. Semester work (Lab performance +Projects) to assess all types of skills

Assessment Schedule

Assessment 1… Written exam Week: (4, 8, 15)

Assessment 2 … Practical exam Week: (13)

Assessment 3… Practical exam quiz Week (13)

Assessment 4… Oral exam	Week: (15)
Assessment 5… Project	Week 12
Assessment 6 Lab performance	Each lab

Weighting of Assessments

First Mid-Term Examination		5 %
Second Mid-Term Examination		15 %
Final-Term Examination		30 %
Oral Examination		10 %
Practical Examination		30 %
. Practical exam	25%	
Practical exam quiz	5%	
Semester Work		10 %
Lab Performance		
Students' Project		
Total		**100%**

6. List of References

6.1. Course Notes

Notes on Industrial Pharmacy II, Mina Ibrahim Tadros

Lab manual: Practical Industrial Pharmacy II, Mina Ibrahim Tadros

6.2. Essential Books (Text Books)

- **Aulton's Pharmaceutics: The design and manufacture of medicines**, Michael Aulton

Publisher: Churchill Livingstone, 4th Edition, 2013.

- **The theory and Practice of Industrial Pharmacy**, Leon Lachman.

Publisher: Lea & Febiger, 4th Edition, 2009.

6.3. Recommended Books

Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard Ansel

Publisher: Lippincott Williams & Wilkins, 10th Edition, 2014.

6.4. Periodicals, Websites, ……etc

Periodicals: Journal of Drug Development and Industrial Pharmacy.

Websites: www.pubmed.com , www.Rxlist.com , www.Pharmweb.com

7. Facilities Required for Teaching and Learning

a. Personal computer equipped with a data show.

b. White board.

c. Internet searching.

Course Coordinator

Dr. Mina Ibrahim Tadros

Head of Department

Prof. Dr. Hussein Ammar

Department Approval Date: September 2014

Quality Control & Quality Assurance (PHT 531)

Course Specifications

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All departments
Department offering the course:	Pharmaceutical Technology Department
Academic year:	2014/2015
Date of specifications approval:	September 2014

A. Basic Information

Course title: Quality control and Quality Assurance

Course Code: PHT 531

Prerequisites: Pharmaceutics 3 (PHT 315)
Instrumental analysis (PHC 224)

Credit Hours: 3 hrs.(2 + 1)

Students' Level/Semester: Fifth year/ 10th semester

Actual teaching hours per week:

Lecture: 2 hrs/week **Practical:** 2 hrs/week **Total:** 4 hrs/week

B. Professional Information

1. Overall Aim of Course

By the completion of this course, the student would have acquired the necessary information about the quality control tests of solid dosage forms (tablets, capsules, effervescent granules and suppositories), semi-solid dosage forms (ointments, creams and gels), liquid dosage forms (solutions, suspensions and emulsions) and sterile dosage forms (parenterals, ophthalmics and aerosols). In addition, he would be aware of the inter-relationship between quality control, quality assurance and good manufacturing practice as well as the concepts of process validation (prospective, retrospective, concurrent and revalidation). In addition, the student will be able to understand the principles of quality control and quality assurance of pharmaceutical products and the correlation between them. The student will know the principles of sampling techniques which are needed prior to applying the necessary analytical methods. The student will acquire information about quality assurance, validation data, and the necessary documentation to proof the identity, quality and purity of drug substance and related drug products. Moreover, the

student will be able to apply the methods to assess the stability of the drug according to ICH guidelines.

2. Intended Learning Outcomes (ILOs)

By the end of the course, the student will be able to:

a- Knowledge and Understanding:

a1. Describe the quality control tests for each dosage form.
a2. Identify the basic concepts and methods of validation.
a3. Differentiate between quality control, quality assurance and good manufacturing practice.
a4. Recognize the basis of Good analytical practice.

b- Intellectual Skills:

b1. Assess the quality of the manufacturing operations involved in pharmaceutical industry.
b2. Distinguish the quality control tests in the different pharmacopeias.
b3. Predict the quality of various products based on the specific tests.
b4. Discuss the documentation and the filing of given products.
b5. Relate the quality control tests of different pharmacopeias (USP, BP and EP).
b6. Point out the quality of the reference substance and standard and estimate their sources.
b7. Apply stability indicating methods on the drug according to ICH guidelines.
b8. Create a suitable sampling plan based on an approved and documented protocol.
b9. Interpret validation schemes.

c- Professional and Practical Skills:

c1. Use the appropriate equipment efficiently, safely and economically.
c2. Carry out the suitable quality control tests for various dosage forms.
c3. Test the standard quality of the finished product accurately.
c4. Apply validation (prospective, retrospective, concurrent & revalidation) effectively.
c5. Select different types of samples following a scheme.
c6. Apply method validation schemes.
c7. Apply stability indicating methods.
c8. Analyze raw and finished products

d- General and Transferable Skills:

d1. Communicate clearly by the appropriate quality and validation terms.
d2. Use numeracy and calculation to solve problems
d3. Write documents satisfying the regulatory requirements.
d4. Work autonomously or with minimum guidance in quality control laboratories.
d5. Manage the time in analytical work effectively.

3. Contents

Week	Topic	No. of hours	Lecture	Practical
One	Q.C. tests of tablets	4	1	
	Introduction on quality control and quality assurance.		1	
	Introduction and assay of ferrous sulfate (Ferrofol® capsules) using colorimetry.			2
Two	Q.C. tests of tablets	4	1	
	Good Analytical Practice & Good Laboratory Practice.		1	
	Application of aqueous acid-base titration to the assay of indomethacin.(Indocid™ capsules)			2
Three	Q.C. tests of capsules and effervescent granules	4	1	
	Analytical control laboratory (Definition, responsibilities, requirements, units).		1	
	Assay of indomethacin (indocid™ capsules)			2
Four	Q.C. tests of suppositories	4	1	
	Type of sampling tools and sampling plans **- First Mid-Term exam**		1	
	EDTA- Titration of zinc (prisoline Zinc eye drops)			2
Five	Q.C. tests of semisolids	4	1	
	Documentation		1	
	Assay of iron-content (Pediatric Ferrous Sulfate Oral Solution)			2
Six	Q.C. tests of solutions	4	1	
	Documentation		1	
	Practical Exam (Part I)			2
Seven	Q.C. tests of suspensions	4	1	
	Analysis of pharmaceutical		1	

	products			
	Q.C. tests of tablets			2
Eight	**Second Midterm Exam**			
Nine	Q.C. tests of emulsions	4	1	
	Validation of analytical methods		1	
	Q.C. tests of suppositories			2
Ten	Q.C. tests of parenterals and ophthalmics	4	1	
	Data elements required for assay validation		1	
	Q.C. tests of effervescent granules			2
Eleven	Q.C. tests of aerosols	4	1	
	Data elements required for assay validation		1	
	Q.C. tests of creams and lotions			2
Twelve	Reasons for validation	4	1	
	Drug degradation and stability of drug in bulk and dosage forms		1	
	Revision			2
Thirteen	Quality assurance	4	1	
	-Forced degradation studies -Stability indicating methods		1	
	Practical Exam (Part II)		1	2
Total no. of hours		**48**	**24**	**24**
Fourteen	University Elective Exams			
Fifteen	Final exams of Faculty			
Sixteen				

4. Teaching and Learning Methods

4.1. Power point lectures.

4.2. Practical Labs.

4.3. Internet search

5. Student Assessment Methods

5.1. Written exam to assess overall knowledge and intellectual skills.

5.2. Practical exam to assess professional and practical skills.

5.3. Practical exam quiz to assess theoretical background of the practical part.

5.4. Oral exam to assess all types of skills (mainly general and transferable skills).

5.5. Semester work (Lab performance) to assess all types of skills.

Assessment Schedule

Assessment 1… Written exam	Week: (4, 8, 15)
Assessment 2 … Practical exam	Week: (13)
Assessment 3… Practical exam quiz	Week (13)
Assessment 4… Oral exam	Week: (15)
Assessment 5…Semester Work (Lab performance)	Each lab

Weighting of Assessments

First Mid-Term Examination		5 %
Second Mid-Term Examination		15 %
Final-Term Examination		30 %
Oral Examination		10 %
Practical Examination		30 %
Practical exam	25%	
Practical exam quiz	5%	
Semester Work		10 %
(lab performance)		
Total		**100%**

6. List of References

6.1. Course Notes

Notes on Quality control of drugs, Mohamed Abdelkawy**.**

Notes on Quality control & quality assurance, Mina Ibrahim Tadros

Lab manual: Practical Quality control, Mohamed Abdelkawy - Mina Ibrahim Tadros

6.2. Essential Books (Text Books)

- **Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems,** Howard Ansel

  Publisher: Lippincott Williams & Wilkins, 10th Edition, 2014.

- **Pharmaceutical process validation**, Nash R.A. and Wachter A.H.

Publisher: Marcel Dekker, 3rd Edition, 2003.

6.3. Recommended Books

- Aulton's Pharmaceutics: The design and manufacture of medicines, Michael Aulton

Publisher: Churchill Livingstone, 4th Edition, 2013.

6.4. Periodicals, Websites, ……etc

Periodicals: Journal of Drug Development and Industrial Pharmacy.

Websites: www.pubmed.com , www.Rxlist.com , www.Pharmweb.com

7. Facilities Required for Teaching and Learning

a. Personal computer equipped with a data show.

b. White board.

c. Internet searching.

d. Laboratory equipped by Spectrophotometers, measuring flasks, burettes, pipettes, measuring cylinders and filter papers.

Course Coordinator

Dr. Mina Ibrahim Tadros

Head of Department

Prof. Dr. Hussein Ammar

Department Approval Date: September 2014

Dermatologicals and Cosmetics (PHT 616)

Course Specifications

Program (s) on which the course is given:	Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program:	All Faculty Departments
Department offering the course:	Pharmaceutical Technology Department
Academic year:	2014/2015
Approval Date:	September 2014

A. Basic Information

Course Title: Dermatologicals and Cosmetics
Course Code: PHT 616
Prerequisites: Pharmaceutics II (PHT 314)
Students' Level/Semester: Elective
Credit hours: 2 (1+1)
Actual teaching hours per week:
Lectures: 1 hr. /week **Practical:** 2hr. /week **Tutorial:** N/A
Total: 3 hr. /week

B. Professional Information

1. Overall Aim of Course

This course aims to get the student aware of the scope of different types of cosmetics and skin products as preparations for care of the skin, their formulation, evaluation and use. Preparations of cosmetics as well as preparations for skin protection are also included in this course.

2. Intended Learning Outcomes (ILOs)

By the end of this course, the student should be able to:

a- Knowledge and Understanding:

a1. List types of creams and skin powders.
a2. Define tooth pastes, nail lacquer, lipstick, baby preparations
a3. Recognize shampoos and hair products, antiperspirant, sun screen, foot care preparations, hair products as well as skin aging, its management and advanced cosmetic preparations.
a4. Summarize the different types of dermatological preparations.
a5. Define anti-skin aging preparations.
a6. Recognize advanced cosmetics preparations.
a7. Differentiate between types of cosmetic preparations.

a8. Design different types of dermatological preparations.

b- Intellectual Skills:

b1. Distinguish different dermatological dosage forms.
b2. Calculate quantity of ingredients needed for dermatological preparations.
b3. Solve problems of prescription.

c- Professional and Practical Skills:

c1. Formulate different types of creams, pastes and lipsticks
c2. Outline the steps needed for dispensing a certain cosmetic preparations.
c5. Predict the most suitable technique for different cosmetic preparations.

d-General and Transferable Skills:

d1. Communicate effectively with others.
d2. Work effectively with others.
d3. Use different resources to update his scientific information.
d4. Counsel patients about the use of skin care products.

3. Contents

Teaching Weeks	Topic	No. of hours	Lecture	Practical
One	Cosmetic creams	3	1	
	Cold cream (Borax-Beeswax)			2
Two	Cosmetic powders	3	1	
	Vanishing cream-Unpigmented foundation cream			2
Three	Lipsticks	3	1	
	Cleansing cream- All purpose cream			2
Four	Dentifrices **First midterm exam**	3	1	
	Shaving preparations			2
Five	Shampoos	3	1	
	Antiperspirant cream- Sun screen			2
Six	Hair products	3	1	
	Acne vulgaris cream			2

Seven	Nail lacquer -Baby preparation	3	1	
	Anti-dandruff cream- Anti-diaper rash cream			2
Eight	**Second midterm exam**			
Nine	Antiperspirants and deodorants	3	1	
	Tooth paste- Clear liquid shampoo			2
Ten	Foot care and hygiene – Sunscreen	3	1	
	Design different types of dermatological preparations. Face powder- Anti-chap sticks- Lipsticks			2
Eleven	Sunscreen-Skin aging and its management	3	1	2
	Revision (Practical)			
Twelve	Advanced cosmetics	3	1	
	Practical exam.			2
Thirteen	Revision	1	1	
Total No. of hours		**34**	**12**	**22**
Fourteen	**University Elective Final Exams**			
Fifteen	**Final Exams of Faculty**			
Sixteen				

4. Teaching and Learning Methods

4.1. Lectures
4.2. Power point presentations
4.3. Seminars
4.4. Practical laboratory sessions

5. Student Assessment Methods

5.1. Written exam. to assess knowledge and intellectual skills
5.2. Practical exam to assess professional and practical skills
5.3. Sheet exams to assess theoretical background of the practical course
5.4. Assignment to assess professional and practical skills.
5.5. Semester Work (Participation) to assess all skills and mainly general and transferrable skills.

Assessment Schedule

Assessment 1 first midterm exam	Week 4
Assessment 2 Second midterm exam	Week 8
Assessment 3 assignment	Week 10
Assessment 4 practical + sheet exam	Week 12
Assessment 5 final written exam	Week 15/16
Assessment 6 Semester Work	(During the semester)

Weighting of Assessments

1st Mid-Term Examination	5 %
2nd Mid-Term Examination	15 %
Final-Term Examination	40 %
Practical Examination	30 %
{Sheet 5%}	
{Practical Exam 20%}	
{Assignment 5%}	
Semester Work	10 %
Total	**100 %**

6. List of References

6.1. Course Notes

Hand out, lab manual

6.2. Essential Books (Text Books)

- Ansel's Pharmaceutical dosage forms and drug delivery systems, nine edition, and publisher-Lippincott Williams Wilkins, 2011.
- Harris for Cosmetics

6.3. Recommended Books

- Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, 20th ed., Lippincott Williams & Wilkins, Philadelphia, 2013.

6.4. Periodicals, Websites …etc

www.pubmed.com
www.rxlist.com
www.cspsa.cpm

7. Facilities Required for Teaching and Learning

Computer equipped with projector, white board.
Facilities for practical: mortars & pestles, glassware, porcelain dishes, etc….

Course Coordinator: Assoc. Pro. Dr. Mona Ibrahim Abd EL Tawab

Head of Department: Prof. Dr. Hussein Ammar

Department Approval Date: September 2014

Applied Industrial Pharmacy (PHT 624)

Course Specifications

Program (s) on which the course is given: Bachelor of Pharmaceutical Sciences and Pharmaceutical Industries
Department offering the program: All Faculty Departments
Department offering the course: Pharmaceutical Technology Department
Academic year: 2014/2015
Approval Date: September 2014

A. Basic Information

Course Title: Applied Industrial Pharmacy **Course Code:** PHT 624
Prerequisites: Industrial Pharmacy II (PHT 523)
Students' Level/Semester: Elective
Credit hours: 2 (1+1)
Actual teaching hours per week:
Lectures: 1hr. /week **Practical:** 2hr. /week **Tutorial:** N/A **Total:** 3hr. /week

B. Professional Information

1. Overall Aim of Course

After completing the course, the student will have learnt the basic knowledge in the area of applied industrial unit operations like crystallization, filtration, emulsification, distillation, mass transfer and fluid flow. The student would be able to investigate the recent applications in nanotechnology, solid dispersions and tablet coating techniques.

2. Intended Learning Outcomes (ILOs)

By the end of the course, the student will be able to:

a- Knowledge and Understanding:

a1. Describe the basic concepts of applied industrial unit operations like crystallization, filtration, emulsification, distillation, mass transfer and fluid flow.
a2. Describe the sequential production steps involved in the production of pharmaceutical products (raw materials, intermediates and finished products).
a3. Enumerate the environmental factors influencing the design of each unit operation.
a4. Identify the experimental variables influencing the production operations.

a5. Identify the recent applications in nanotechnology, solid dispersions and tablet coating techniques

b- Intellectual Skills:

b1.Evaluate the employed techniques (emulsification, solid dispersion and nanotechnology) to improve the solubility of poorly water soluble drugs.
b1. Recognize the problems emerging during the production of drug crystals.
b3. Convert the laboratory units to their corresponding industrial units.
b4. Solve problems related to mass transfer and fluid flow.
b5. Develop the possible solutions to the problems encountered within filtration.
b6. Analyze the variables influencing distillation.

c- Professional and Practical Skills:

c1. Plot suitable sketches for commonly used equipment in crystallization, filtration, emulsification, distillation, mass transfer and fluid flow.
c2. Use the appropriate equipment efficiently, safely and economically.
c3. Choose the best equipment for tablet coating.
c4. Design an appropriate method to develop drug nanoparticles.
c5. Justify the reasons for selecting the equipment for mass transfer and fluid flow.

d- General and Transferable Skills:

d1. Demonstrate creativity in plotting novel industrial equipment.
d2. Use numeracy and calculation to convert laboratory units to the appropriate industrial units.
d3. Communicate clearly by appropriate industrial terms.
d4. Use different resources to get updated with the most recent advances in industrial equipment and unit operations.

3. Contents

Week	Topic	No. of hours	Lecture
One	Crystallization theory	**2**	**2**
Two	Crystallization equipment	**2**	**2**
Three	Filtration techniques	**2**	**2**

Four	Filtration equipment - first mid-term exam	**2**	**2**
Five	Emulsification	**2**	**2**
Six	Distillation concepts	**2**	**2**
Seven	Distillation equipment	**2**	**2**
Eight	**Second Midterm Exam**		
Nine	Mass transfer and Fluid flow	**2**	**2**
Ten	Nanotechnology: introduction	**2**	**2**
Eleven	Nanotechnology applications	**2**	**2**
Twelve	Tablet coating techniques	**2**	**2**
Thirteen	Tablet coating techniques	**2**	**2**
Total no. of hours		**24**	**24**
Fourteen	University Elective Final Exams		
Fifteen	Final Exams of Faculty		
Sixteen			

4. Teaching and Learning Methods

4.1. Power point lectures.

4.2. Practical Labs.

4.3. Internet search

5. Student Assessment Methods

5.1. Written exam to assess overall knowledge and intellectual skills as well as professional skills.

5.2. Quiz to assess the theoretical background as well as professional skills.

5.3. Oral presentations to assess the general and transferable skills.

5.4. Oral exam to assess all types of skills (mainly general and transferable skills).

5.5. Semester work (Participation) to assess all types of skills.

Assessment Schedule

Assessment 1 first mid-term exam	Week 4
Assessment 2 Second mid-term exam	Week 8
Assessment 3 Oral presentations	Week 12
Assessment 4 final written exam	Week 15
Assessment 5 Oral exam	Week 15
Assessment 6 Semester Work	During the semester

Weighting of Assessments

First Mid-Term Examination	5 %
Second Mid-Term Examination	15 %
Final-Term Examination	30 %
Oral Examination	10 %
Oral presentations	30%
Semester Work	10 %
Total	**100%**

6. List of References

6.1. Course Notes

Notes on Applied Industrial Pharmacy, Mina Ibrahim Tadros

6.2. Essential Books (Text Books)

- ***Aulton's Pharmaceutics*: The design and manufacture of medicines**, Michael Aulton

Publisher: Churchill Livingstone, 4th Edition, 2013.

- The theory and Practice of Industrial Pharmacy, Leon Lachman.

Publisher: Lea & Febiger, 4th Edition, 2009.

6.3. Recommended Books

Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard Ansel

Publisher: Lippincott Williams & Wilkins, 10th Edition, 2014.

6.4. Periodicals, Websites, ……etc

Periodicals: Journal of Drug Development and Industrial Pharmacy.

Websites: www.pubmed.com , www.Rxlist.com , www.Pharmweb.com

7. Facilities Required for Teaching and Learning

a. Personal computer equipped with a data show.

b. White board.

c. Internet searching.

Course Coordinator
Dr. Mina Ibrahim Tadros

Head of Department
Prof. Dr. Hussein Ammar

Department Approval Date: September 2014