Course Specification of Industrial Pharmacy II

I. Course Identification and General Information:							
1	Course Title:	Industrial Pharmacy II					
2	Course Number & Code:	Ph21025					
3	Credit hours:3hrs	C.H				Total	
		Theoretical	Practical	Training	Seminar		
		2	1			3	
4	Study level / semester at which course is offered:	Level: - Fifth Year /Second Semester					
5	Pre –requisite (if any):	Industrial Pharmacy I					
6	Co –requisite (if any):						
7	Programs in which course is offered:	Bachelor of pharmacy					
8	Language of teaching the course:	English					
9	Department in which course is offered:	Pharmaceutics and Industrial Pharmacy					
10	Location of teaching the course:	Faculty of Pharmacy- Sana`a university					
11	Prepared by:	Prof. Dr. Maged Alwan					
12	Date of approval:						

II. Course description:

Course provide students with the necessary knowledge in the area of pharmaceutical technology, and to help them to understand the fundamentals and importance of the unit operations in the manufacture of dosage forms such as mixing, drying, milling and particle size analysis

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علوان	ا.د. محمود البريهي	ا.د.ماجد علوان	د.خالد الشوبة	ا.م.د. هدى العماد	ا.د. القاسم محمد عباس

III. Intended learning outcomes (ILOs) of the course:

At the end of this course, the students will be able to:

1. Distinguish appropriate good manufacturing practice (GMP) and Quality Control (QC) criteria to aseptic and sterile production facilities and other pharmaceutical industry
2. Identify the principles of quality assurance (QA) in education and of quality assurance of pharmaceutical processes and products.
3. **Recall the principles** of various instruments and techniques including manufacturing, packaging, labeling and storing processes in pharmaceutical industry
4. Describe the equipment's of filtration, crystilization, distillation and air purification used in industrial pharmacy with their operation and applications.
5. Recommend good manufacturing practice (GMP), good laboratory practice (GLP), good clinical practice (GCP) and good safety practice (GSP) guidelines in pharmaceutical technology, pharmaceutical research and pharmacy practice..
6. Assess the relationship between equipment design and product characteristics
7. Select the best equipment and/or operational line to perform pharmaceutical operation.
8. Diagrammatically design the studied equipments for each operation.
9. Manage pharmaceutical instruments and equipment safely and efficiently and solve commonly encountered problems in pharmaceutical manufacturing processes
10. Collect data about different equipment used in pharmaceutical industry and their operation.
11. Conduct research studies and analyze results.
12. Plan strategies to fulfill workplace pharmaceutical needs
13. Retrive and evaluate information from different sources.
14. Work in groups and independently.

IV. Intended learning outcomes (ILOs) of the course:

(A) Knowledge and Understanding:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Knowledge and Understanding.

Program Intended Learning Outcomes (Sub-PILOs) in: Knowledge and Understanding	Course Intended Learning Outcomes (CILOs) in: Knowledge and Understanding
After completing this program, students will be able to:	**After completing this course, students will be able to:**

A1-	Recognize the principles of physical, chemical, clinical, social, behavioral, health and pharmaceutical sciences.	**a1-**	Distinguish appropriate good manufacturing practice (GMP) and Quality Control (QC) criteria to aseptic and sterile production facilities and other pharmaceutical industry
A2-	Recognize the physicochemical properties,	**a2-**	Identify the principles of quality assurance (QA) in
	preparation, structure activity relationship (SAR), toxicity and the modern methods of analysis of various substances of chemical and natural products of therapeutic potential as well as the basic principle of drug discovery, design and development		education and of quality assurance of pharmaceutical processes and products.
A4-	Recognize the pharmaceutical dosage form design and the quality control of pharmaceutical formulations according to GMP and pharmacopeia requirements to support the pharmaceutical industries and research.	**a3**	Recall the principles of various instruments and techniques including manufacturing, packaging, labeling and storing processes in pharmaceutical industry.
		a4	Describe the equipment's of filtration, crystilization, distillation and air purification used in industrial pharmacy with their operation and applications.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Knowledge and Understanding to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Knowledge and Understanding		Teaching strategies/methods to be used	Methods of assessment
completing this course, students will be able to:		1. Lectures using white board and data show. 2. Practical session using laboratory equipment 3. Research assignments 4. Case study 5. Discussion session	**1-Written exam** To assess understanding, intellectual, professional **2-Practical exam** To assess professional and practical skills **3-Oral** To assess Knowledge, understanding, intellectual skills, general skills and confidence **4-Quizzes** To assess Knowledge, understanding, intellectual skills
a1-	Distinguish appropriate good manufacturing practice (GMP) and Quality Control (QC) criteria to aseptic and sterile production facilities and other pharmaceutical industry		
a2-	Identify the principles of quality assurance (QA) in education and of quality assurance of pharmaceutical processes and products		
a3-	Recall the principles of various instruments and techniques including manufacturing, packaging, labeling and storing processes in pharmaceutical industry.		

a4-	Describe the equipment's of filtration, crystilization, distillation and air purification used in industrial pharmacy with their operation and applications.		**5-Case study** To assess the skills of problem-solving and date presentation 6-Reports

(B) Intellectual Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Intellectual skills

Program Intended Learning Outcomes (Sub-PILOs) in Intellectual skills		Course Intended Learning Outcomes (CILOs) of Intellectual Skills	
After completing this program, students will be able to:		**After completing this course, students will be able to:**	
B1-	Consolidate the chemical, biochemical and physiological principles to construct the pharmacophores of the structure and their effect on the stability, pharmacokinetic and pharmacodynamic profiles of the drug.	**b1-**	Recommend good manufacturing practice (GMP), good laboratory practice (GLP), good clinical practice (GCP) and good safety practice (GSP) guidelines in pharmaceutical technology, pharmaceutical research and pharmacy practice..
B3-	Design different types of safe and effective pharmaceutical dosage forms and develop novel methods of qualitative and quantitative analytical and biological analysis for pharmaceutical and biopharmaceutical products that support pharmaceutical research.	**b2-**	Assess the relationship between equipment design and product characteristics.
B5-	Interpret the prescriptions, patient and clinical data, Analysis all the encountered pharmaceutical problems and plan the strategies for their solution, to develop the health care.	**b3-**	Select the best equipment and/or operational line to perform pharmaceutical operation
		b4	Diagrammatically design the studied equipments for each operation

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Intellectual Skills to Teaching Methods and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Intellectual Skills.	Teaching strategies/methods to be used	Methods of assessment

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After completing this course, students will be able to:		1.Lecture 2.Practical using laboratory equipment 3.Research assignments	1.Written exam 2.Oral 3.Quizzes
b1-	Recommend good manufacturing practice (GMP), good laboratory practice (GLP), good clinical practice (GCP) and good safety practice (GSP) guidelines in pharmaceutical technology, pharmaceutical research and pharmacy practice..		
b2-	Assess the relationship between equipment design and product characteristics.		
b3-	Select the best equipment and/or operational line to perform pharmaceutical operation		
b4-	Diagrammatically design the studied equipments for each operation.		

(C) Professional and Practical Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Professional and Practical Skills

Program Intended Learning Outcomes (Sub-PILOs) in Professional and Practical Skills		Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills	
After completing this program, students will be able to:		**After completing this course, students will be able to:**	
C1-	Operate different pharmaceutical equipments and instruments and use emerging technologies in preformulation, formulation, packaging, storage and analysis of pharmaceutical products according to GLP, GSP and cGMP guidelines.	**c1-**	Manage pharmaceutical instruments and equipment safely and efficiently and solve commonly encountered problems in pharmaceutical manufacturing processes
C3-	Perform extraction, isolation, purification, identification, standardization, formulation of natural products and assure their rational use.	**c2**	Collect data about different equipment used in pharmaceutical industry and their operation.
C5-	Conduct research studies and utilize the results in different pharmaceutical fields.	**c3**	Conduct research studies and analyze results.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Professional and Practical Skills to Teaching and Assessment Methods:

		Methods of assessment

Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills		Teaching strategies/methods to be used	
After completing this course, students will be able to:		1.Practical session using laboratory equipment 2.Discussion session 3.Research	1.Oral 2.Quizzes 3.Case study
c1-	Manage pharmaceutical instruments and equipment safely and efficiently and solve commonly encountered problems in pharmaceutical manufacturing processes		
c2	Collect data about different equipment used in pharmaceutical industry and their operation.		
c3	Conduct research studies and analyze results.		

(D) General / Transferable Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: General and Transferable skills

Program Intended Learning Outcomes (PILOs) in General / Transferable skills		Course Intended Learning Outcomes (CILOs) in General / Transferable skills	
After completing this program, students will be able to:		After completing this course, students will be able to:	
D2	Employ proper documentation and filing systems in different pharmaceutical fields	d1-	Plan strategies to fulfill workplace pharmaceutical needs
D3.	Develop financial, market management, writing, presentation and time management skills as well as creativity, critical thinking, problem solving and decision making abilities.	d2	Retrieve and evaluate information from different sources.
D5.	Apply information and communication technology and working effectively in a team.	d3	Work in groups and independently

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of General and Transferable skills to Teaching and Assessment Methods:

		Methods of assessment

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Course Intended Learning Outcomes (CILOs) in General and Transferable Skills		Teaching strategies/methods to be used	
After completing this course, students will be able to:		1. Lectures using white board and data show. 2. Practical session 3. Research assignments 4. Discussion session	Oral Case study Quizzes Reports
d1-	Plan strategies to fulfill workplace pharmaceutical needs		
d2-	Retrieve and evaluate information from different sources.		
d3	Work in groups and independently		

V. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1	cGMP current good manufacture practice	a1, a2, b1,d1-3	Introduction to current good manufacture practice Starting materials Personnel Building and facilities Complaints and product recalls	1	2

2	cGMP current good manufacture practice	a1, b1, d2,d1-3	Documentations Self-inspection and quality audits Quality assurance and quality control	1	2
3	cGMP current good manufacture practice	b2, d1, d2, ,d1-3	Introduction to validation of manufacturing process Types of process validation Validation of sterile products	1	2
4	Filtration	a4, b3, b4,d1-3	Introduction Mechanism Factors affecting Filter media Filter aids Filtration equipment's Leaf filters Rotator continuous Meta filters Filter press Centrifugal filtration	1	2
5	Air Purification	a4, b3, b4,d1-3	Ways in air purification used in pharmaceutical industry. Effectiveness processes	1	2
			used to purify air. Mechanism of air purification. 1-Filtration. 2-Sedimentation 3-Electricalprecipitation 4-Scrubbing.		

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6	Crystallization	a4, b2, b4 ,d1-3	Definition Crystal forms and habit Solubility curves Factors affecting rate of crystal growth Caking of crystals Crystallization equipment	1	2
7	**Mid Term Exam.**	a1-4,b1-4		1	2
8	Distillation	a4, b2, b4 ,d1-3	Concepts Application Types Equipment's.	1	2
9	Industrial Plants Hazards & Safety	a1-2,b1, ,d1-3	Industrial hazards Types of hazards Noise, equipment noise sources ,level & potential control solutions Industrial effluent testing and treatment Waste Water Treatment	1	2
10	Pharmaceutical packaging	a3,b4,d1-3	Ideal properties, function, , and types of packaging Influence of packaging materials. Glass, metal, plastics, paper & board Films, foils & laminates Rubber Closures Labeling Packaging lines, packaging	2	4
			area, packaging equipment. Package testing & stability.		

11	Standard Operating Procedures (SOPs)	a3,a4,b3, d1, d3	SOP for dissolution apparatus Objective Scope Responsibilities Procedure:	1	2
12	Pharmaceutical Herbal Formulations	a2,a3,b3, d1, d2	Categorization of herbal medicines Quality Safety W.H.O. Guidelines for Quality Standardized Herbal Formulations Advantages of Herbal Medicine Ash values, Extractive values determination Potential Toxic contaminants in herbal formulation Contamination of herbal formulation WHO Guidelines for Potential contaminants in Herbal Formulations Heavy Metal Arsenic Cadmium Lead Microbial Contamination Instrumentation	2	4
13		a3, b3 ,d1-3	The important products that manufactured by microorganism in pharmaceutical industry Vaccine Antibody Antibiotics Probiotics	2	4

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	Role microorganism in Pharmaceutical Industry		Source of Probiotics and Effect on Bod Enzyme & Vit. production Bacteriocins Chelation Antimicrobial copper alloy surfaces Phage therapy Antimicrobial activity & disinfection Medical devices Cosmetic microbiology		
14	**Final Exam**	a1-4,b1-4		1	2
Number of Weeks /and Units Per Semester				**16**	**32**

b- Practical Aspect:

Order	Practical Tasks	CILOs (symbols)	Number of weeks	Contact hours
1	1. Drying and drying control. 2. Drying equibments (selection)	c1-2,d1-4	**1**	**2**
2	1. Extraction (Batch percolator + Packed column tower).	c1-3,d1-4	**1**	**2**
3	Crystallization , formation , growth Saturation and Super saturation.	c1-3,d1-4	**1**	**2**
4	Liquid preparation, volume variation, density and viscosity	c1-3,d1-4	**1**	**2**
5	1. Sedimentation rate 2. Calculation.	c1-3,d1-4	**1**	**2**
6	Pre-formulation studies on acetaminophen / acetyl salicylic acid Or any drug.	c1-3,d1-4	**1**	**2**
7	**Mid. Exam**	c1-3	**1**	**2**
8	Preparation and evaluation of acetaminophen tablets	c1-3,d1-4	**2**	**4**
9	Coating of tablets- film coating of tables/granules	c1-3,d1-4	**1**	**2**

10	Preparation and evaluation of Tetracycline capsules Or Other drugs.	c1-3,d1-4	**1**	**2**
11	Preparation of Ascorbic Acid injection Or other drugs.	c1-3,d1-4	**1**	**2**
12	Preparation of Eye drops/ and Eye ointments.	c1-3,d1-4	**1**	**2**
13	Quality control test of marketed Pharmaceutical preparation / selection	c1-3,d1-4	**1**	**2**
14	Revision in factory and labs	c1-3,d1-4	**1**	**2**
16	**Final Practical Exam.**	c1-3	**1**	**2**
Number of Weeks /and Units Pr Semester			**16**	**32**

VI. a-Teaching strategies of the course:

1. Lectures using white board and data show.
2. Practical session using laboratory equipment
3. Research assignments
4. Case study
5. Discussion session

b-Assessment Methods:

1-Written exam To assess understanding, intellectual, professional
2-Practical exam To assess professional and practical skills
3-Oral To assess Knowledge, understanding, intellectual skills, general skills and confidence
4-Quizzes To assess Knowledge, understanding, intellectual skills
5-Case study To assess the skills of problem-solving and date presentation 6-Reports

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	**a1-4, b1-4,d1-4**	Sporadic through the semester	**10**
2	Reports	**c1-3, d1-4**		

III. Schedule of Assessment Tasks for Students During the Semester:

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No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
1.	**Attendance, Participation and quizzes**	**All Weeks**	10	7%	a1-4,b1-4, **d1-4**
2.	**Oral Tests and Homeworkassignments**	Sporadic through the semester	10	7%	a1-4, b1-4, **d1-4**
3.	**Attendance, Practical Reports**	**All Weeks**	15	10%	c1-3
4.	**Practical mid-semester exam**	11th	15	10%	c1-3
5.	**Theoretical mid-semester exam**	6th	30	20%	a1-4, b1-4
6.	**Final Exam (theoretical)**	16th	50	33%	a1-4, b1-4
7.	**Final Exam (practical)**	16th	20	13%	c1-3
	Total		**150**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
Two contact hours per week	None

X. Learning Resource (MLA style or APA style)S:

1- Required Textbook(s) (maximum two)

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	1. , lea & Febiger, (2002),The Theory and Practice of Industrial Pharmacy 2nd Ed, Philadelphia. 2. Sarfaraz K.Niazi ,(2009),Handbooks of Pharmaceutical Manufacturing Formulations 2nd Ed.,
2- Recommended Readings and Reference Materials	
	Rockville, MD,2008,- United States Pharmacopoeia, The United States Pharmacopeial Convention, Inc.,. , 31st ed., U.S.A. Reynold, J.E.F., 2000, Martindale, The Extra Pharmacopoeia, The Pharmaceutical Press, 32nd ed., London.
3- Essential References	
	- Remington:, 2000, The Science and Practice of Pharmacy, Alfonso, R.G. (Ed.), 20th ed. The University of the Sciences in Philadelphia, U.S.A., - Allen, L. V., Popovich, N. G., and Ansel, H. C., 2005, Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th Edition ,Lippincott Williams & Wilkins Publishers.
4- Electronic Materials and Web Sites *etc*.	
	http://www.pharmaceutical technology.com http://www.sciencedirect.com http://www.pubmed.com http://www.google.com
5- Other Learning Material:	
	Study tour: A visit to pharmaceutical industries will be an integrated part of the syllabi

XI. Facilities Required:

1 - Accommodation:	- Well-equipped lecture halls with data show facilities, whiteboards, net connection, etc. - Well-equipped laboratories with all required equipment and reagents.
2 - Computing resources:	- Computer laboratory with internet facilities.

XII. Course Improvement Processes:

1- Strategies for obtaining student feedback on effectiveness of teaching

- Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester.
- Meeting with students and faculty (once per semester).

2- Other strategies for evaluation of teaching by the instructor or by the department.	
	▪ Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester. ▪ Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).
3- Processes for improvement of teaching.	
	▪ Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions. ▪ Exploring any possible defects in the course that might encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.
4- Processes for verifying standards of students' achievement	
	▪ Checking of a sample of students' work by an independent faculty member. ▪ Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution. ▪ Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments). ▪ Regular follow-up of laboratory logbooks to assess the practical achievement of students.
5- Procedures for periodically reviewing of course effectiveness and planning for improvement	
	▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course development plans	
	▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

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XIII. Course Policies: (including plagiarism, academic honesty, attendance etc)	
The University Regulations on academic misconduct will be strictly enforced. Please refer to ----------	
1	**Class Attendance:** ▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	**Tardy:** - Roll will be called in the very beginning of each lecture and practical class. Retardation for more than three weeks without a reasonable excursion, the student involved shall not be allowed to attend the class any longer and consequently shall be considered to be absent.
3	**Exam Attendance/Punctuality:** ▪ Exam attendance is obligatory unless being excused by the department and faculty. ▪ Absence from assignments or exams will dealt with according to the general policy of the university.
4	**Assignments & Projects:** ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	**Cheating:** ▪ Punishment of cheating will be according to the general policy of the university in this respect.
6	**Plagiarism:** ▪ Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	**Other policies:** ▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.

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Course Plan of Industrial Pharmacy II

I. - Information about Faculty Member Responsible for the Course:							
Name of Faculty Member	Prof. Dr. Maged Alwan	Office Hours					
Location & Telephone No.		SAT	SUN	MON	TUE	WED	THU
E-mail							

II. Course Identification and General Information:						
1-	Course Title:	Industrial Pharmacy II				
2-	Course Number & Code:	Ph2921				
3-	Credit hours:3hrs	C.H				Total
		Th.	Seminar	Pr.	F. Tr.	
		2	-	2		3
4-	Study level/year at which this course is offered:	5th year/2nd semester				
5-	Pre –requisite (if any):	Industrial Pharmacy I				
6-	Co –requisite (if any):					
7-	Program (s) in which the course is offered	Bachelor of Pharmacy				
8-	Language of teaching the course:	English				
9-	System of Study:	Semesters				
10-	Mode of delivery:	Regular				
11-	Location of teaching the course:	Faculty of Pharmacy-Sana'a University				

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III. Course description:

Course provide students with the necessary knowledge in the area of pharmaceutical technology, and to help them to understand the fundamentals and importance of the unit operations in the manufacture of dosage forms such as mixing, drying, milling and particle size analysis

IV. Intended learning outcomes (ILOs) of the course:

At the end of this course, the students will be able to:

15. Distinguish appropriate good manufacturing practice (GMP) and Quality Control (QC) criteria to aseptic and sterile production facilities and other pharmaceutical industry
16. Identify the principles of quality assurance (QA) in education and of quality assurance of pharmaceutical processes and products.
17. **Recall the principles** of various instruments and techniques including manufacturing, packaging, labeling and storing processes in pharmaceutical industry
18. Describe the equipment's of filtration, crystilization, distillation and air purification used in industrial pharmacy with their operation and applications.
19. Recommend good manufacturing practice (GMP), good laboratory practice (GLP), good clinical practice (GCP) and good safety practice (GSP) guidelines in pharmaceutical technology, pharmaceutical research and pharmacy practice..
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27. Retrive and evaluate information from different sources.
28. Work in groups and independently.

V. Course Content:

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1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1	cGMP current good manufacture practice	a1, a2, b1,d1-3	Introduction to current good manufacture practice Starting materials Personnel Building and facilities	1	2
			Complaints and product recalls		
2	cGMP current good manufacture practice	a1, b1, d2,d1-3	Documentations Self-inspection and quality audits Quality assurance and quality control	1	2
3	cGMP current good manufacture practice	b2, d1, d2, ,d1-3	Introduction to validation of manufacturing process Types of process validation Validation of sterile products	1	2
4	Filtration	a4, b3, b4,d1-3	Introduction Mechanism Factors affecting Filter media Filter aids Filtration equipment's Leaf filters Rotator continuous Meta filters Filter press Centrifugal filtration	1	2

5	Air Purification	a4, b3, b4,d1-3	Ways in air purification used in pharmaceutical industry. Effectiveness processes used to purify air. Mechanism of air purification. 1-Filtration. 2-Sedimentation 3-Electricalprecipitation 4-Scrubbing.	1	2
6	Crystallization	a4, b2, b4 ,d1-3	Definition Crystal forms and habit Solubility curves Factors affecting rate of crystal growth	1	2
			Caking of crystals Crystallization equipment		
7	**Mid Term Exam.**	a1-4,b1-4		1	2
8	Distillation	a4, b2, b4 ,d1-3	Concepts Application Types Equipment's.	1	2
9	Industrial Plants Hazards & Safety	a1-2,b1, ,d1-3	Industrial hazards Types of hazards Noise, equipment noise sources ,level & potential control solutions Industrial effluent testing and treatment Waste Water Treatment	1	2

10	Pharmaceutical packaging	a3,b4,d1-3	Ideal properties, function, , and types of packaging Influence of packaging materials. Glass, metal, plastics, paper & board Films, foils & laminates Rubber Closures Labeling Packaging lines, packaging area, packaging equipment. Package testing & stability.	2	4
11	Standard Operating Procedures (SOPs)	a3,a4,b3, d1, d3	SOP for dissolution apparatus Objective Scope Responsibilities Procedure:	1	2
12	Pharmaceutical Herbal Formulations	a2,a3,b3, d1, d2	Categorization of herbal medicines Quality Safety	2	4

			W.H.O. Guidelines for Quality Standardized Herbal Formulations Advantages of Herbal Medicine Ash values, Extractive values determination Potential Toxic contaminants in herbal formulation Contamination of herbal formulation WHO Guidelines for Potential contaminants in Herbal Formulations Heavy Metal Arsenic Cadmium Lead Microbial Contamination Instrumentation		
13	Role microorganism in Pharmaceutical Industry	a3, b3 ,d1-3	The important products that manufactured by microorganism in pharmaceutical industry Vaccine Antibody Antibiotics Probiotics Source of Probiotics and Effect on Bod Enzyme & Vit. production Bacteriocins Chelation Antimicrobial copper alloy surfaces Phage therapy Antimicrobial activity & disinfection Medical devices Cosmetic microbiology	2	4

14	**Final Exam**	a1-4,b1-4		1	2
Number of Weeks /and Units Per Seme ster				**16**	**32**

b- Practical Aspect:

Order	Practical Tasks	CILOs (symbols)	Number of weeks	Contact hours
1	1. Drying and drying control. 2. Drying equibments (selection)	c1-2,d1-4	**1**	**2**
2	1. Extraction (Batch percolator + Packed column tower).	c1-3,d1-4	**1**	**2**
3	Crystallization , formation , growth Saturation and Super saturation.	c1-3,d1-4	**1**	**2**
4	Liquid preparation, volume variation, density and viscosity	c1-3,d1-4	**1**	**2**
5	1. Sedimentation rate 2. Calculation.	c1-3,d1-4	**1**	**2**
6	Pre-formulation studies on acetaminophen / acetyl salicylic acid Or any drug.	c1-3,d1-4	**1**	**2**
7	**Mid. Exam**	c1-3	**1**	**2**
8	Preparation and evaluation of acetaminophen tablets	c1-3,d1-4	**2**	**4**
9	Coating of tablets- film coating of tables/granules	c1-3,d1-4	**1**	**2**
10	Preparation and evaluation of Tetracycline capsules Or Other drugs.	c1-3,d1-4	**1**	**2**
11	Preparation of Ascorbic Acid injection Or other drugs.	c1-3,d1-4	**1**	**2**
12	Preparation of Eye drops/ and Eye ointments.	c1-3,d1-4	**1**	**2**
13	Quality control test of marketed Pharmaceutical preparation / selection	c1-3,d1-4	**1**	**2**
14	Revision in factory and labs	c1-3,d1-4	**1**	**2**

16	**Final Practical Exam.**	c1-3	**1**	**2**
Number of Weeks /and Units Per Semester			**16**	**32**

VI. a-Teaching strategies of the course:

1. Lectures using white board and data show.
2. Practical session using laboratory equipment
3. Research assignments
4. Case study
5. Discussion session

b-Assessment Methods:

1-Written exam To assess understanding, intellectual, professional
2-Practical exam To assess professional and practical skills
3-Oral To assess Knowledge, understanding, intellectual skills, general skills and confidence
4-Quizzes To assess Knowledge, understanding, intellectual skills
5-Case study To assess the skills of problem-solving and date presentation 6-Reports

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	**a1-4, b1-4,d1-4**	Sporadic through the semester	**10**
2	Reports	**c1-3, d1-4**		

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
8.	**Attendance, Participation and quizzes**	**All Weeks**	10	7%	a1-4,b1-4, **d1-4**

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9.	**Oral Tests and Homeworkassignments**	Sporadic through the semester	10	7%	a1-4, b1-4, **d1-4**
10.	**Attendance, Practical Reports**	**All Weeks**	15	10%	c1-3
11.	**Practical mid-semester exam**	11th	15	10%	c1-3
12.	**Theoretical mid-semester exam**	6th	30	20%	a1-4, b1-4
13.	**Final Exam (theoretical)**	16th	50	33%	a1-4, b1-4
14.	**Final Exam (practical)**	16th	20	13%	c1-3
	Total		**150**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
Two contact hours per week	None

X. Learning Resource (MLA style or APA style)S:

6- Required Textbook(s) (maximum two)

1. , lea & Febiger, (2002),The Theory and Practice of Industrial Pharmacy 2nd Ed, Philadelphia.
2. Sarfaraz K.Niazi ,(2009),Handbooks of Pharmaceutical Manufacturing Formulations 2nd Ed.,

7- Recommended Readings and Reference Materials

Rockville, MD,2008,- United States Pharmacopoeia, The United States Pharmacopeial Convention, Inc.,. , 31st ed., U.S.A.
Reynold, J.E.F., 2000, Martindale, The Extra Pharmacopoeia, The Pharmaceutical Press, 32nd ed., London.

8- Essential References

	- Remington:, 2000, The Science and Practice of Pharmacy, Alfonso, R.G. (Ed.), 20th ed. The University of the Sciences in Philadelphia, U.S.A., - Allen, L. V., Popovich, N. G., and Ansel, H. C., 2005, Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th Edition ,Lippincott Williams & Wilkins Publishers.
9- Electronic Materials and Web Sites *etc*.	
	http://www.pharmaceutical technology.com http://www.sciencedirect.com http://www.pubmed.com http://www.google.com
10- Other Learning Material:	
	Study tour: A visit to pharmaceutical industries will be an integrated part of the syllabi

XI. Facilities Required:	
1 - Accommodation:	- Well-equipped lecture halls with data show facilities, whiteboards, net connection, etc. - Well-equipped laboratories with all required equipment and reagents.
3 - Computing resources:	- Computer laboratory with internet facilities.
XII. Course Improvement Processes:	
6- Strategies for obtaining student feedback on effectiveness of teaching	
	▪ Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester. ▪ Meeting with students and faculty (once per semester).
7- Other strategies for evaluation of teaching by the instructor or by the department.	
	▪ Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester. ▪ Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).
8- Processes for improvement of teaching.	

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	□ Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions. □ Exploring any possible defects in the course that might encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.
9- Processes for verifying standards of students' achievement	
	▪ Checking of a sample of students' work by an independent faculty member. ▪ Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution. ▪ Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments). ▪ Regular follow-up of laboratory logbooks to assess the practical achievement of students.
10- Procedures for periodically reviewing of course effectiveness and planning for improvement	
	▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course development plans	
	▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

XIII. Course Policies: (including plagiarism, academic honesty, attendance etc)	
The University Regulations on academic misconduct will be strictly enforced. Please refer to ----------	
1	**Class Attendance:** ▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.

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2	**Tardy:** - Roll will be called in the very beginning of each lecture and practical class. Retardation for more than three weeks without a reasonable excursion, the student involved shall not be allowed to attend the class any longer and consequently shall be considered to be absent.
3	**Exam Attendance/Punctuality:** ▪ Exam attendance is obligatory unless being excused by the department and faculty. ▪ Absence from assignments or exams will dealt with according to the general policy of the university.
4	**Assignments & Projects:** ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	**Cheating:** ▪ Punishment of cheating will be according to the general policy of the university in this respect.
6	**Plagiarism:** ▪ Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	**Other policies:** ▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.

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