Republic of Yemen
Ministry of Higher Education and Scientific Research
Sana'a University
Faculty of Pharmacy
Quality Assurance Unit

الجمهورية اليمنية
وزارة التعليم العالي والبحث العلمي
جامعة - صنعاء
كلية الصيدلة
وحدة ضمان الجودة

Course Specification of Industrial Pharmacy I

I. Course Identification and General Information:							
1	Course Title:	Industrial Pharmacy I					
2	Course Number & Code:	Ph2921					
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 /First Semester					
5	Pre –requisite (if any):	Pharmaceutics I,II,III and IV					
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:

This Course provides students with the necessary knowledge in the area of pharmaceutical technology, and helps 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.

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

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

1. Illustrate all parts and importance of pharmaceutical plants
2. Acquire the principles of pharmaceutical unit operations performed in pharmaceutical industry like, mixing, drying, size reduction and evaporation
3. Describe the equipment's of heat transfer, evaporation, drying, mixing, size reduction, size enlargement and size analysis, used in industrial pharmacy with their operation and applications.
4. Select the most appropriate equipment used for certain unit operations.
5. Classify all equipment used in heat transfer, evaporation, mixing ,drying, size reduction, size enlargement and size analysis and pharmaceutical preparation
6. Perform the most important tests in heat transfer, evaporation, mixing, drying, size reduction, enlargement and size analysis.
7. Collect data about different equipment used in pharmaceutical industry and their operation.
8. Conduct research studies and analyze results.
9. Assess the proper storage conditions for raw materials and finished pharmaceutical products.
10. Manage a suitable methodology to operate the different equipment.
11. Solve the problems encountered in the manufacture of dosage forms.
12. Work effectively as a part of team in order to fulfill certain project.
13. Demonstrate critical thinking and problem solving in different theoretical and practical situations.
14. Present industrial data in a graphical form

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-	Illustrate all parts and importance of pharmaceutical plants
A2-	Recognize the physicochemical properties, 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	a2	Acquire the principles of pharmaceutical unit operations performed in pharmaceutical industry like, mixing, drying, size reduction and evaporation
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	Describe the equipment's of heat transfer, evaporation, drying, mixing, size reduction, size enlargement and size analysis, 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 **5-Case study** To assess the skills of problem-solving and date presentation 6-Reports
a1-	Illustrate all parts and importance of pharmaceutical plants		
a2-	Acquire the principles of pharmaceutical unit operations performed in pharmaceutical industry like, mixing, drying, size reduction and evaporation		
a3	Describe the equipment's of heat transfer, evaporation, drying, mixing, size reduction, size enlargement and size analysis, used in industrial pharmacy with their operation and applications.		

(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-**	Select the most appropriate equipment used for certain unit operations.
B3-	Design different types of safe and effective pharmaceutical dosage forms and develop novel methods of analysis for pharmaceutical and biopharmaceutical products that support pharmaceutical research.	**b2-**	Classify all equipment used in heat transfer, evaporation, mixing ,drying, size reduction, size enlargement and size analysis and pharmaceutical preparation

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
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-	Select the most appropriate equipment used for certain unit operations.		
b2-	Classify all equipment used in heat transfer, evaporation, mixing ,drying, size reduction, size enlargement and size analysis and pharmaceutical preparation		

(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 pre-formulation, formulation, packaging, storage and analysis of pharmaceutical products according to GLP, GSP and cGMP guidelines.	c1-	Perform the most important tests in heat transfer, evaporation, mixing, drying, size reduction, enlargement and size analysis.
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.
		c4	Assess the proper storage conditions for raw materials and finished pharmaceutical products.

Teaching And Assessment Methods For Achieving Learning Outcomes:

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

Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		1.Practical session using laboratory equipment	1.Oral 2.Quizzes 3.Case study
c1-	Classify all equipment used in heat transfer, evaporation, mixing ,drying, size reduction, size enlargement and size analysis and pharmaceutical preparation		

c2-	Collect data about different equipment used in pharmaceutical industry and their operation	2.Discussion session 3.Research	
c3-	Conduct research studies and analyze results.		
c4	Assess the proper storage conditions for raw materials and finished pharmaceutical products.		

(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:**	
D1-	Practice independent learning needed for continuous professional development	**d1-**	Manage a suitable methodology to operate the different equipment.
D2-	Employ proper documentation and filing systems in different pharmaceutical fields	**d2**	Solve the problems encountered in the manufacture of dosage forms.
D3-	Develop financial, market management, writing, presentation and time management skills as well as creativity, critical thinking, problem solving and decision making abilities.	**d3**	Work effectively as a part of team in order to fulfill certain project.
D5-	Apply information and communication technology and working effectively in a team.	**d4**	Demonstrate critical thinking and problem solving in different theoretical and practical situations.
		d5	Present industrial data in a graphical form

Teaching And Assessment Methods For Achieving Learning Outcomes:

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

Course Intended Learning Outcomes (CILOs) in General and Transferable Skills		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		2. Lectures using white board and data show. 2 Practical session 3. Research assignments 4. Discussion session	Oral Case study Quizzes Reports
d1-	Manage a suitable methodology to operate the different equipment.		
d2-	Solve the problems encountered in the manufacture of dosage forms.		
d3	Work effectively as a part of team in order to fulfill certain project.		
d4	Demonstrate critical thinking and problem solving in different theoretical and practical situations		
d5	Present industrial data in a graphical form		

V. Course Content:

1 – Course Topics/Items:

B – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1	Parts of Pharmaceutical Industry and Location	**a1-3,b1, d1-5**	Organization Chart of Industries Important department Plant location Factors affecting on plant location Plant layout Factors influencing on layout Objectives of plant layout Principles of plant layout Steps involved in plant layout Classification of plant layout	1	2
2	Plant Design from the Standpoint of Safety	**a1, d1-5**	-Location -Arrangement of building -Overhead clearance -Building & Equipment's -Processes -Special safety protection equipment -Fire protection	1	2
3	Intro. to Ind. Processing	**a2,b2, d1**	-Pharmaceutical Plant Design -Reasons for increasing large scale manufacture. -Breakdown of Processes:	1	2
4	Heat Transfer.	**a3**, **b2**, b4, **d2**	Conduction Convection Radiation Fourier's law Units & Conversion Thermal conductivity A-Through a plane wall B-Through a composite wall:	1	2

			C-Through Thin-walled pipes and tubes: D-Through thick-walled pipes and tubes: Thermal insulation: Source of heat energy: Types of steam: Equipment's I- Design of heating equipment Heat exchanger.		
5	Evaporation.	**a3**, **b2**, b4, **d2**	Definition. Factors affecting evaporation. A-Natural circulating evaporators. B-Forced circulation evaporators. C-Film evaporators.	1	2
6	Mixing & Mixing Equip.	**a3**, **b2**, b4, **c1**, **d2**	Definition: Objective: Types of Mixing. Classification of mixing. Factors influencing mixing. Mixing Operation: Classification of equipment for mixing Solid-solid, solid-liquid and liqui –liquid mixers.	1	2
7	**Mid Term Exam.**	a1-3,b1-4		1	2
8	Process validation of Semi-solid dosage forms	**a3**, **b1, d3**	General Processes. Process Validation Program. Why, when and who performs it? Validation Protocol. Process Validation Option:	1	2

			Semisolids manuf. consideration I -Flow diagram. II - Unit Operation for semisolid System. III - Filling & Packaging Operation Sampling Plan: Monitoring Output:		
9	Drying and drying Equip.	**a3**, **b2**, b4, **d2**	Definition. Non thermal drying. Importance of drying. Theory of Drying: Relative Humidity. Equilibrium moisture content (EMC): Types of dryers: Dryers for dilute solutions, suspensions and slurries Dryers for damp solid materials Continuous and Batch dryers.	1	2
10	Size Reduction.	**a3**, **b2**, b4, **d2**	Definitions Objective Factors affecting size reduction: Pharmaceutical Application of Size Reduction: METHODS OF SIZE REDUCTION	1	2
11	Size Enlargement.	**a3**, **b2**, b4, **d2**	Objectives. Granulation Techniques of Making Tablets by Pre Compression:	1	2
12	Particle Size Analysis.	**a3**, **b2**, b4, **d2**	Importance: Methods Microscopy. Sieving.	1	2

			Sedimentation techniques Optical and electrical sensing zone method Laser light scattering techniques Cyclone separators Elutriation		
13	Materials used in Construction of Pharmaceutical Industries	**a1, b2, d1-5**	Objective. Metal and metal alloy Glass Fluoropolymers GMP Guidelines WHO / GMP guidelines GMP / FDA guidelines	3	6
14	**Final Exam**	a1-3,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	Mixing with V-shaped & double cone blenders (study the effect of the type of mixer, mixing time and mixing RPM)	c1-3,d1-5	**1**	**2**
2	1. Size reduction (Hammer mill + Ball mill + Cutter mill). 2. Size enlargement (Reciprocating horizontal granulator + Perforated basket granulator). 3. Size enlargement (Chilsonator).	c1-4,d1-5	**2**	**4**
3	1. Wet granulation with planetary mixer. 2. Dry granulation.	c1-4,d1-5	**1**	**2**
4	1. Evaporation (Problems)	c1-4,d1-5	**1**	**2**
5	1. Tableting of granules using a single / a rotary tablet press. 2. Measurement of tablet weight variation, hardness and friability for the prepared tablets and 2 market products.	c1-4,d1-5	**2**	**4**
6	**Mid. Exam**	c1-4	**1**	**2**

7	Heat transfer (Problems,).	c1-4,d1-5	**1**	**2**
8	1. Preparation of a calibration curve of a model drug E.g (Paracetamol). 2. Measurement of tablet disintegration and dissolution.	c1-4,d1-5	**1**	**2**
9	Drying (Fluidized bed dryer + Tray dryer + Lyophilizer + Standard spray dryer) and problems	c1-4,d1-5	**1**	**2**
10	1. Assay of drug content using UV spectrophotometer. 2. Demonstration of HPLC apparatus.	c1-4,d1-5	**1**	**2**
11	1. Particle size analyses, sieving. 2. Capsule feeding process, size, identification,	c1-4,d1-5	**2**	**4**
12	Revision in factory and labs	c1-4,d1-5	**1**	**2**
13	**Final Practical Exam**	c1-4	**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. Project tasks for groups of students (10 each) to prepare a report related to the topics lectured and make presentation for that report.

b- Assessment Methods:

1- Written exams including the mid- and final-term exams 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- Collaborative projects assignment to assess the ability to work in group, solve problems, present data and discussion
5. Quizzes To assess Knowledge, understanding, intellectual skills

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark

1	Homework Assignments	**a1-3, b1-4, d1-5**	Sporadic through the semester	**10**
2	Reports	**c1-4, d1-5**		

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)
2	**Participation and quizzes**	**1-12**	**10**	7%	a1-3,b1-4, **d1-5**
3	**Collaborative projects assignment**	9th week	**10**	7%	a1-3,b1-4, **d1-5**
	Mid practical- exam, reports and attendance	**All weeks**	**30**	20%	c1-4
4	**Mid-semester exam**	**8**	**30**	20%	a1-3,b1-4
	Final practical- exam	**16**	**20**	13%	c1-4
5	**Final theoretical Exam**	**16**	**50**	33%	a1-3,b1-4
	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)

1. The Theory and Practice of Industrial Pharmacy 2nd Ed, lea & Febiger , Philadelphia (2002).
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*.**
	Periodicals as Drug Development and Industrial Pharmacy, International Journal of Pharmaceutics. http:/www.polymerfactory.com, http:/www.capsugel.com Companies home pages 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.

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 I

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 I				
2-	Course Number & Code:	Ph2921				
3-	Credit hours:	C.H				Total
		Th.	Seminar	Pr.	F. Tr.	
		2	-	2		3
4-	Study level/year at which this course is offered:	5th Year/1st Semester				
5-	Pre –requisite (if any):	Pharmaceutics I-IV				
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				

III. Course description:

This course provides students with the necessary knowledge in the area of pharmaceutical technology, and helps 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:

1. Illustrate all parts and importance of pharmaceutical plants
2. Acquire the principles of pharmaceutical unit operations performed in pharmaceutical industry like, mixing, drying, size reduction and evaporation
3. Describe the equipment's of heat transfer, evaporation, drying, mixing, size reduction, size enlargement and size analysis, used in industrial pharmacy with their operation and applications.
4. Select the most appropriate equipment used for certain unit operations.
5. Classify all equipment used in heat transfer, evaporation, mixing ,drying, size reduction, size enlargement and size analysis and pharmaceutical preparation
6. Perform the most important tests in heat transfer, evaporation, mixing, drying, size reduction, enlargement and size analysis.
7. Collect data about different equipment used in pharmaceutical industry and their operation.
8. Conduct research studies and analyze results.
9. Assess the proper storage conditions for raw materials and finished pharmaceutical products.
10. Manage a suitable methodology to operate the different equipment.
11. Solve the problems encountered in the manufacture of dosage forms.
12. Work effectively as a part of team in order to fulfill certain project.
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14. Present industrial data in a graphical form

V. Course Content:

1 – Course Topics/Items:

B – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1		a1-3,b1, d1-5	Organization Chart of Industries Important department	1	2

	Parts of Pharmaceutical Industry and Location		Plant location Factors affecting on plant location Plant layout Factors influencing on layout Objectives of plant layout Principles of plant layout Steps involved in plant layout Classification of plant layout		
2	Plant Design from the Standpoint of Safety	**a1, d1-5**	-Location -Arrangement of building -Overhead clearance -Building & Equipment's -Processes -Special safety protection equipment -Fire protection	1	2
3	Intro. to Ind. Processing	**a2,b2, d1**	-Pharmaceutical Plant Design -Reasons for increasing large scale manufacture. -Breakdown of Processes:	1	2
4	Heat Transfer.	**a3**, **b2**, b4, **d2**	Conduction Convection Radiation Fourier's law Units & Conversion Thermal conductivity A-Through a plane wall B-Through a composite wall: C-Through Thin-walled pipes and tubes: D-Through thick-walled pipes and tubes: Thermal insulation: Source of heat energy: Types of steam: Equipment's I- Design of heating equipment Heat exchanger.	1	2
5	Evaporation.	**a3**, **b2**, b4, **d2**	Definition.	1	2

			Factors affecting evaporation. A-Natural circulating evaporators. B-Forced circulation evaporators. C-Film evaporators.		
6	Mixing & Mixing Equip.	**a3**, **b2**, b4, **c1**, **d2**	Definition: Objective: Types of Mixing. Classification of mixing. Factors influencing mixing. Mixing Operation: Classification of equipment for mixing Solid-solid, solid-liquid and liqui –liquid mixers.	1	2
7	**Mid Term Exam.**	a1-3,b1-4		1	2
8	Process Validation of Semi-solid Dosage Forms	**a3**, **b1, d3**	General Processes. Process Validation Program. Why, when and who performs it? Validation Protocol. Process Validation Option: Semisolids manuf. consideration I -Flow diagram. II - Unit Operation for semisolid System. III - Filling & Packaging Operation Sampling Plan:	1	2

			Monitoring Output:		
9	Drying and Drying Equip.	**a3**, **b2**, b4, **d2**	Definition. Non thermal drying. Importance of drying. Theory of Drying: Relative Humidity. Equilibrium moisture content (EMC): Types of dryers: Dryers for dilute solutions, suspensions and slurries Dryers for damp solid materials Continuous and Batch dryers.	1	2
10	Size Reduction.	**a3**, **b2**, b4, **d2**	Definitions Objective Factors affecting size reduction: Pharmaceutical Application of Size Reduction: METHODS OF SIZE REDUCTION	1	2
11	Size Enlargement.	**a3**, **b2**, b4, **d2**	Objectives. Granulation Techniques of Making Tablets by Pre Compression:	1	2
12	Particle Size Analysis.	**a3**, **b2**, b4, **d2**	Importance: Methods Microscopy. Sieving. Sedimentation techniques Optical and electrical sensing zone method Laser light scattering techniques Cyclone separators Elutriation	1	2
13	Materials used in Construction of Pharmaceutical Industries	**a1, b2, d1-5**	Objective. Metal and metal alloy Glass Fluoropolymers	3	6

			GMP Guidelines WHO / GMP guidelines GMP / FDA guidelines		
14	**Final Exam**	a1-3,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	Mixing with V-shaped & double cone blenders (study the effect of the type of mixer, mixing time and mixing RPM)	c1-3,d1-5	**1**	**2**
2	1. Size reduction (Hammer mill + Ball mill + Cutter mill). 2. Size enlargement (Reciprocating horizontal granulator + Perforated basket granulator). 3. Size enlargement (Chilsonator).	c1-4,d1-5	**2**	**4**
3	1. Wet granulation with planetary mixer. 2. Dry granulation.	c1-4,d1-5	**1**	**2**
4	1. Evaporation (Problems)	c1-4,d1-5	**1**	**2**
5	1. Tableting of granules using a single / a rotary tablet press. 2. Measurement of tablet weight variation, hardness and friability for the prepared tablets and 2 market products.	c1-4,d1-5	**2**	**4**
6	**Mid. Exam**	c1-4	**1**	**2**
7	Heat transfer (Problems,).	c1-4,d1-5	**1**	**2**
8	1. Preparation of a calibration curve of a model drug E.g (Paracetamol). 2. Measurement of tablet disintegration and dissolution.	c1-4,d1-5	**1**	**2**
9	Drying (Fluidized bed dryer + Tray dryer + Lyophilizer + Standard spray dryer) and problems	c1-4,d1-5	**1**	**2**
10	1. Assay of drug content using UV spectrophotometer.	c1-4,d1-5	**1**	**2**

	2. Demonstration of HPLC apparatus.			
11	1. Particle size analyses, sieving. 2. Capsule feeding process, size, identification,	c1-4,d1-5	**2**	**4**
12	Revision in factory and labs	c1-4,d1-5	**1**	**2**
13	**Final Practical Exam**	c1-4	**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. Project tasks for groups of students (10 each) to prepare a report related to the topics lectured and make presentation for that report.

b- Assessment Methods:

1- Written exams including the mid- and final-term exams 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- Collaborative projects assignment to assess the ability to work in group, solve problems, present data and discussion
5. Quizzes To assess Knowledge, understanding, intellectual skills

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	**a1-3, b1-4, d1-5**	Sporadic through the semester	**10**
2	Reports	**c1-4, d1-5**		

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)
2	**Participation and quizzes**	**1-12**	**10**	7%	a1-3,b1-4, **d1-5**
3	**Collaborative projects assignment**	9th week	**10**	7%	a1-3,b1-4, **d1-5**
	Mid practical- exam, reports and attendance	**All weeks**	**30**	20%	c1-4
4	**Mid-semester exam**	**8**	**30**	20%	a1-3,b1-4
	Final practical- exam	**16**	**20**	13%	c1-4
5	**Final theoretical Exam**	**16**	**50**	33%	a1-3,b1-4
	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. The Theory and Practice of Industrial Pharmacy 2nd Ed, lea & Febiger , Philadelphia (2002).
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.*	
	Periodicals as Drug Development and Industrial Pharmacy, International Journal of Pharmaceutics. http:/www.polymerfactory.com, http:/www.capsugel.com Companies home pages 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.	
	▪ 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.
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.