



In the name of GOD

Department of Pharmaceutics

School of pharmacy, Iran University of Medical Sciences

Course title: Internship of Pharmaceutical Industry (primary)

Course code:

Credit: 2

Prerequisite: pharmaceutics 1-5 theoretical and practical, Microbiological control theoretical and practical, Physicochemical control theoretical and practical

First Semester: Sep 2023

Course Instructors: Dr.Hamed Morad, Dr. Mehdi Ansari, Dr. Ahmadreza Barazesh

Responsible Instructor: Dr. Hamed Morad

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References:

- 1- USP
- 2- BP
- 3- Cleaning validation manual. Haider SI
- 4- Pharmaceutical packaging technology. Dean DA
- 5- GMP/ISO quality audit manual for healthcare manufacturers and their suppliers. Steinbor L
- 6- Quality assurance of pharmaceuticals, WHO the latest edition



- 7- Sterile product manufacturing facilities. ISPE
- 8- Quality systems and controls for pharmaceuticals. Sarker DK
- 9- Cleanroom technology, fundamentals of design, testing and operation.
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Student assessment:

- 1- Active attendance and report: 50%
- 3-Final exam (multiple-choice questions, descriptive questions): 50%

- All classes will be held in Besarati (Eastern 7) street, North Shahin Boulevard

Course title:

	subject	Method	Professor	Date
1	- Primary requirements for establishing a pharmaceutical & biopharmaceutical industry company (premises & equipment) - Contract manufacturing	Theory	Dr. Morad	26 Sep
2	- Organization chart in pharmaceutical company - Introduction of departments -Interdepartmental communications	Theory	Dr. Morad	10 Oct
3	- Warehouse department qualifications, requirements, responsibilities and all related considerations	Theory	Dr. Morad	17 Oct
4	- Warehouse department qualifications, requirements, responsibilities and all related considerations	Theory	Dr. Morad	24 Oct
5	- Production department qualifications, requirements, responsibilities and all related considerations	Theory	Dr. Morad	31 Oct
6	- Water treatment - HVAC	Theory	Dr. Morad	7 Nov



7	- Documentation, filling routine forms (Deviation, change control, batch reconciliation, CAPA, log books &...)	Theory	Dr. Morad	14 Nov
8	Visiting of General Directorate of Food, Drug and Medical Equipment Control Laboratories	Practical	Dr. Morad	21 Nov
9	-R&D department qualifications, requirements, responsibilities and all related considerations	Theory	Dr. Barazesh	28 Nov
10	- QC & QA department qualifications, requirements, responsibilities and all related considerations	Theory	Dr. Barazesh	5 Dec
11	- Visiting Behestan Pakhsh pharmaceutical company	Practical	Dr. Morad	12 Dec
12	Visiting Tehran Shimi Or Osveh pharmaceutical companies	Practical	Dr. Morad	19 Dec

The contribution of the grade of the professors of the course

professors	Exercise & report	Final Exam	Sum
Dr Morad	8	8.5	16.5
Dr. Barazesh	0	3.5	3.5