Islamic Republic of Iran

Ministry of Health and Medical Education

Supreme Council for Medical Sciences Planning

Doctoral Program (Ph.D.) for pharmaceutical biomaterials

(General specifications, curriculum, course syllabus, and evaluation method)

Approved by the 92nd meeting of the Supreme Council for Medical Sciences Planning, on 1403/04/02

Resolution issued at the 92nd meeting of the Supreme Council for Medical Sciences Planning on 2/4/1403 regarding:

The curriculum for the Doctorate (Ph.D.) course in the field of pharmaceutical biomaterial:

1. The Ph.D. curriculum in the field of pharmaceutical biomaterials was approved by a majority of vote

2. The educational curriculum for the Doctoral of philosophy Degree (Ph.D.) in the field of pharmaceutical biomaterial is practicable from the communication statement date.

Verified by:

1. **Dr. Bahram Daraei,** Secretary of the Pharmacy and Specialized Education Council
2. **Dr. Gholamreza Hassanzad,** Secretary of the Supreme Council for Medical Sciences Planning
3. **Dr. Abolfazl Bagherifar,** Deputy Director of Education and Secretary of the Medical and Specialized Education Council

The decision issued in the 92nd meeting of the Supreme Council for Medical Sciences Planning on 1403/04/02 regarding the educational program for the Doctorate (Ph.D.) course in the field of **Pharmaceutical biomaterial** is correct and should be implemented.

Dr. Bahram Einollahi,

Minister of Health and Medical Education and Chairman of the Supreme Council for Medical Sciences Planning of the Republic of Iran

Ph.D. Educational Program in the Field of Pharmaceutical Biomaterials

Field: Pharmaceutical Biomaterials
Degree: Doctor of Philosophy (Ph.D.)
Specialized Secretariat: Secretariat of the Council for Pharmaceutical and Specialized Education

At its 92nd session dated June 22, 2024 (1403/4/2 in the Iranian calendar), the Supreme Council of Medical Education Planning approved the educational program for the Ph.D. in Pharmaceutical Biomaterials based on the proposed plan confirmed by the Secretariat of the Council for Pharmaceutical and Specialized Education. The program was approved in five chapters (General Characteristics, Curriculum, Course Syllabi, Standards, and Program Evaluation), as detailed in the attached document, and it was decreed that:

1. The Ph.D. educational program in Pharmaceutical Biomaterials shall be mandatory from the date of notification for all universities and higher education institutions in the country that meet the following criteria:

a) Universities and higher education institutions operating under the supervision of the Ministry of Health and Medical Education.

b) Institutions officially authorized by the Ministry of Health and Medical Education and established in accordance with relevant regulations, thus subject to the resolutions of the Supreme Council of Medical Education Planning.

c) Other higher education institutions established under specific laws and required to adhere to the academic regulations of the Islamic Republic of Iran.

2. From the date of notification of this program, all existing educational courses and similar programs related to the Ph.D. in Pharmaceutical Biomaterials at the institutions mentioned in Article 1 shall be null and void. These universities and institutions may establish and implement the new program in accordance with the specified regulations.
3. The general characteristics of the curriculum, course syllabi, standards, and evaluation methods for the Ph.D. program in Pharmaceutical Biomaterials are hereby communicated in five chapters for implementation.

Chapter 1

Educational curriculum in Biopharmaceuticals at the Doctoral (Ph.D.) Level

Names of the members of the Ph.D. curriculum Review Committee for the pharmaceutical biomaterials:

Mr. Dr. Ismail Haririan	Tehran University of Medical Sciences
Mr. Dr. Khosrow Adibkia	Tabriz University of Medical Sciences
Mr. Dr. Bijan Malaekeh Nikoi	Mashhad University of Medical Sciences
Ms. Dr. Fatemeh Ahmadi	Shiraz University of Medical Sciences
Mr. Dr. Seyed Abolfazl Mostafawi	Isfahan University of Medical Sciences
Ms. Dr. Katayoun Derakhshandeh	Hamadan University of Medical Sciences
Mr. Dr. Ghobad Mohammadi	Kermanshah University of Medical Sciences
Mr. Dr. Mohammad Akrami	Tehran University of Medical Sciences
Mr. Dr. Mazda Rad Malekshahi	Tehran University of Medical Sciences
Mr. Dr. Mojtaba Mojtahedzadeh	Tehran University of Medical Sciences
Ms. Dr. Mona Navaei Nigjeh	Tehran University of medical Sciences
Mr. Dr. Mohammad Mehdi Taheri	Tehran University of Medical Sciences
Ms. Dr. Somayeh Handali	Tehran University of Medical Sciences
Mr. Dr. Hamed Ghawimi	Zanjan University of Medical Sciences
Mr. Dr. Ali Ramezani	Zanjan University of Medical Sciences

Colleagues of the Secretariat of the Supreme Council for Medical Sciences Planning:

Mr. Noorallah Akbari Dastak:

Deputy Secretary of the Secretariat of the Supreme Council for Medical Sciences Planning

Ms. Raheleh Daneshnia:

Expert in charge of the Secretariat of the Supreme Council for Medical Sciences Planning

Ms. Zohreh Ghorbani:

Expert of the Secretariat of the Supreme Council for Medical Sciences Planning

List of members and invitees present at the 289th meeting of the Supreme Council for Medical Sciences Planning at 1403/02/23:

Attendees:

Dr. Abolfazl Bagherifard

Dr. Gholamreza Hassanzadeh

Dr. Fereydoun Nouhi

Dr. Bahram Daraei

Dr. Hossein Dargahi

Dr. Gholamreza Asghari

Dr. Behrouz Attarbashi Moghadam

Dr. Rasoul Farast Kish

Dr. Hossein Vahidi

Dr. Seyed Mehdi Rozat

Dr. Soleiman Ahmadi

Dr. Mehdi Tehranidost

Dr. Babak Sabet

Dr. Kazem Ghahramanzadeh

Dr. Mohsen Abbasi

Dr. Seyed Alireza Mortazavi

Dr. Mohammad Mehdi Nowruz Shamsi

Dr. Saeed Changizi Ashtiani

Dr. Mohammad Reza Azizi (Representative of the Medical System Organization)

Dr. Seyed Hashem Daryabari (Representative of the Deputy for Treatment)

Dr. Farhad Adhami Moghadam (Representative of the Deputy for Science Islamic Azad University Medicine)

Mr. Dr. Mohammad Reza Rahbar (Honorable Representative of the Deputy of Health)

Mr. Dr. Gholamreza Heidari

Ms. Dr. Elahe Malekan Rad

Ms. Dr. Mitra Zolfaghari

Ms. Dr. Hourieh Mohammadi

Ms. Dr. Seyedeh Sara Mirfazli (Faculty Member of Iran University of Medical Sciences)

Ms. Dr. Seyedeh Rabab Elhami (Representative of the Deputy of Research)

Invited guests:

Mr. Dr. Ismail Haririan

Mr. Norolleh Akbari Dastak

List of attendees of the Supreme Council for Medical Sciences Planning at the time of approval of the curriculum of the field of pharmaceutical biomaterials at the Ph.D. level Ph.D.

Mr. Bahram Einollahi

Mr. Abolfazl Bagherifard

Mr. Abbas Ebadi

Mr. Gholamreza Hassanzadeh

Mr. Mohsen Nafer

Mr. Fereydoun Nouhi

Mr. Nader Mumtazmanesh

Mr. Soleiman Ahmadi

Mr. Seyed Mehdi Rozat

Mr. Behrouz Attarbashi Moghadam

Mr. Hossein Dargahi

Mr. Bahram Daraei

Mr. Kazem Ghahramanzadeh

Mr. Babak Sabet

Mr. Reza Yazdani

Mr. Saeed Changizi Ashtiani

Mr. Mohammad Mehdi Nowruz Shamsi

Mr. Mohammad Rahmati

Mr. Hassan Bakhtiari

Mrs. Elahe Malekan Rad

Mrs. Hourieh Mohammadi Ahuri

Introduction

The evolution of universities over time and the very important role they play in the sustainable development of societies show the importance of creating transformation and innovation in their educational and research functions. Today, the new generation of universities, while maintaining traditional educational and research functions, have become a productive institution of science and technology that leads to problem solving and the creation of wealth and added value. They play a very important role in responding to the needs of the industry of society, producing and developing knowledge-based products and advanced technologies. In this fully dynamic system, interdisciplinary and intradisciplinary training and skills are provided according to the needs of the learners and in line with the proposed project, so that the student acquires the necessary capabilities to conduct problem-oriented applied research and acquires the ability to convert ideas into products.

Biomaterials are non-living materials that are designed to treat or diagnose diseases by interacting with the biological system of the body. This type of study, with a history of 50 years, is taught as a field of study at the master's and doctoral levels of Biomaterials Sciences, and Biomaterials Engineering in reliable universities around the world.

Biomaterials, which is a unique interdisciplinary specialty (with an interdisciplinary, multidisciplinary and trans disciplinary essence); pursues the goals of development, expansion, creation of software and hardware infrastructure, training efficient specialists, eliminating the country dependence and localization in the country, and creating the necessary platform for the flourishing and emergence of valuable and efficient innovations, following logical and purposeful principles.

Over the past 44 years in the world and considering the increasing importance of biomaterials, there has been a great deal of attention paid to education and research in the subcategory of biomaterials such as polymers, ceramics, metals, composites and glass. Biomaterials has been established in most reliable universities in Europe, America and even Turkey, Malaysia, India and ..., as specialized trends in dedicated departments or in the form of research centers and biomaterial quality control institutes.

Increasing in the findings and deep understanding of biological systems, advance in the knowledge of the biomolecules and cells with materials interactions, as well as significant progress in the design and manufacture of new materials with controllable and predictable properties, have prompted pharmaceutical researchers to engage in the design, production, and application of biocompatible materials with biological systems with a clinical perspective for the purpose of diagnosis, prevention, and treatment.

The interdisciplinary field of pharmaceutical biomaterial, as the intersection of modern chemistry, molecular cell biology, engineering methods and regenerative medicine, along with pharmaceutics, promises to optimize novel drug delivery systems. The use of mechatronics and the use of mechanical elements of sensors and actuators, along with electronic knowledge, allows pharmaceutical science to explore new methods for drug/gene monitoring in the *in vivo* environment, which in the long term will lead to a revolution in the pharmaceutical industry. In such a way that achieving a personalized drug strategy by designing specialized miniature

pharmaceutical factories in specialized hospitals is another goal of this field. The manufacture and production of robotic drugs is also the other goals of this field.

Although this proposal was initially considered impossible and idealistic, but the design, production, supply and use of endoscopic capsules for diagnosing disorders and lesions of the digestive system made it a reality. In addition, the use of sub-sets of mechatronics knowledge, namely MEMS (Micro Electromechanical Systems) and NEMS (Nano Electromechanical Systems), along with polymeric, lipid, ceramic, mineral, metal and composite drug carriers, gave the novel ideas of pharmaceutical specialists a realistic look. There is hope that in a short period of time, the way to the specific monitoring and targeting of drug/gene carriers within the cells and tissues of the body will be paved by applying the field of pharmaceutical biomaterials.

In order to achieve the goals of the comprehensive program of justice, excellence, and efficiency in medical education; the following can be mentioned as expected goals and extensive educational and research activities in this field, in addition to promoting the science of pharmaceutical biomaterial and its localization in the country:

1. Responding to the needs of design, production and evaluation of biopharmaceuticals in the country

2. Moving towards creating self-sufficiency and preventing the outflow of foreign exchange

3. Making the country's creative and young human resources more efficient and preventing brain drain

4. Correcting the traditional trend of postgraduate research and establishing a policy to make student projects efficient in order to solve the country's problems and needs

5. Establishing financial independence for government postgraduate education in the field of biopharmaceuticals and creating capital for the implementing institution through accepting students based on their interest and ability to implement a research project between the universities and various industrial pharmaceutical centers which are providing the fund

6. Creating technical knowledge to produce a new product or supplement and evaluate existing products as the goal of a thesis which are approved by educational, research, commercial, industrial and private centers in the country.

Field Name:

Pharmaceutical Biomaterials (Ph.D.)

Doctor of Philosophy (PhD)

Field Definition:

Biomaterials refers to any type of material, whether natural or synthetic, such as metals, polymers, ceramics, and composites, that is used in medicine and pharmacy by interfering and interacting with biological systems for treatment and diagnosis. These bioactive and natural

body-imitating materials at the micro and nano scale precisely mimic the body's natural functions and structures and are used for treatment, repair, reconstruction, or replacement in the human body.

The field of biomaterials encompasses natural or synthetic functional materials that are widely used in pharmaceutical science due to their exceptional biocompatibility. This interdisciplinary science combines pharmaceutics and biomaterials with a focus on strategies for material manipulation and explores the materials science and clinical applications of various biomaterials in the pharmaceutical field. Advances in biomaterial sciences have significantly improved drug delivery systemsand increased the efficacy of various drug compounds such as antibodies, peptides, vaccines, and drugs. Polymer-based biomaterials, especially natural polymers that exhibit bioactive properties, have been introduced as promising drug delivery systems due to their potential benefits.

The PhD program in pharmaceutical bioaterials has created a coordinated set of educational, research, and entrepreneurial activities by utilizing and linking various sciences such as medicine, chemistry, physics, biology, nanotechnology, and mechatronics alongside pharmaceutics. Using the most uptodate scientific topics to design, manufacture, and utilize materials that can be used in biological systems, with a special focus on the topic of drug carriers, is one of the goals of this field.

Conditions and procedure for admission to the course:

- Passing the entrance exam is in accordance with the rules and regulations of the Ministry of Health, Treatment and Medical Education.
- Doctor of Pharmacy, Medicine, Dentistry
- Doctorate of Veterinary Medicine and Laboratory Sciences
- Master's Degree in Biotechnology, All Majors in Nanotechnology, Medical Nanotechnology, Pharmaceutical Nanotechnology, Polymer Engineering, Molecular Cell Biology, Physiology, Medical Physics, Biophysics, Clinical Biochemistry, Biomechanics, Medical Immunology, Genetics, Human Genetics, Chemistry (All Majors), Tissue Engineering, Medical Biotechnology, Chemical Engineering, Materials Engineering, Pharmaceutical Engineering and Medical Engineering (Biomaterials), Bioinformatics, Medical Bioinformatics
- Continuous Master's Degree in Pharmacy
- Non-continuous Master's Degree in Pharmacy (on condotion that one has a Bachelor's Degree in Pharmacy)

Note:

Educational degree obtained from universities abroad must have been approved by the Ministry of Health, Medical Education or the Ministry of Research Science and Technology.

For information on the latest changes in the accepted academic degrees and exam materials and entrance exam coefficients for each academic year, refer to the Specialized Doctorate (PhD) Examination Booklet for the Medical Sciences Majors for that academic year.

History and evolution of the course in the world and Iran:

pharmaceutical biomaterials include natural and synthetic materials that are highly compatible with the body used in pharmaceuticals, which lead to the development of drug delivery and the enhancement of the efficacy of drugs containing peptide, antibodies ... in the clinic.

The history of biopharmaceuticals back to 50 years ago when the first hydrogel was invented and the first drug conjugation was performed, where ceramic polymer materials and metal alloys were replaced with natural materials. The title of biomaterial itself is also one of the oldest scientific fields used by ancient Egyptians and Iranians. Over the past 50 years of practical use of biomaterials and drugs, biopharmaceuticals have gradually established their position as the driving force behind the leap in the prevention, treatment and diagnosis of various diseases. Currently, a large number of scientific departments and research centers in universities and scientific centers around the world are dedicated to this, and the following examples illustrate some of these activities:

University of Oslo - Department of Biomaterials

The Department of Biomaterials at the Institute of Clinical Dentistry is actively involved in research relevant to clinical dentistry and medicine.

Massachusetts Institute of Technology (MIT) - Biomaterials

MIT's Biomaterials department engages in the engineering of substances directed at therapeutic or diagnostic purposes through the use of living organisms.

Johns Hopkins University - Biomaterials

The Department of Materials Science and Engineering at Johns Hopkins University conducts biomaterials research projects, spanning drug delivery systems to functional nanofiber scaffolds.

University of Manchester - Biomaterials

Researchers at the Department of Materials, University of Manchester, are involved in developing advanced biomaterials for various applications, including regenerative medicine.

University of Gothenburg - Department of Biomaterials

The Department of Biomaterials at the University of Gothenburg focuses on in depth studies of bioactive materials based on bioglass, bioceramic, and biopolymers.

FUNGLASS - Department of Biomaterials

FUNGLASS'S Department of Biomaterials concentrates on in-depth studies of various bioactive materials based on bioglass, bioceramic, and biopolymers.

Prominent biomaterials research centers:

Centre for Advanced Materials and Biomaterials Research (CAMBR)

Located at the University of Western Ontario, CAMBR brings together over 50 research groups to address significant materials challenges.

Trent Centre for Biomaterials Research

This research program at Trent University explores the creation and use of biomaterials within an ethical framework, integrating science, social science, and humanities

Research Center for Macromolecules and Biomaterials

Based at the National Institute for Materials Science (NIMS), Japan, this center focuses on the research and development of soft polymer materials supporting various applications.

Biomaterials and Microfluidics Core Facility - Pasteur Institute

Led by Samy Gobaa, this core facility is equipped for the design, production, and testing of microfluidic devices, contributing to biomaterials and microfluidics research.

Biomedical Materials Research Area - Royce Institute

The Royce Institute's Biomedical Materials Research Area aims to accelerate the discovery, manufacture, and translation of biomedical materials, enhancing the field.

Biomaterials Research Community - Duke Biomedical Engineering

Duke University's Biomaterials research community, supported by various centers and programs, contributes to advancements in the field, including materials research.

Institute for Biomaterials, Drug Delivery and Regenerative Medicine

Located at the University of Texas at Austin, this institute serves as a focal point for impactful activities in research, education, and service within biomaterials and drug delivery.

Centre for Biomedical and Healthcare Engineering - Mines Saint-Étienne

This center, based in France, engages in research fields such as biomechanics of soft tissues, medical textiles, implants, and engineering of biomaterials

Biomaterials and Pharmaceutical Materials (BPM) - University of Minnesota

The BPM program at UMN-CSE focuses on the synthesis and characterization of novel hard and soft materials and composites for pharmaceutical applications

Regenerative Medicine Biomaterials and Biomolecules Facility - Mayo Clinic

Located in Rochester, Minnesota, this facility provides resources for manufacturing in the field of regenerative medicine biomaterials and biomolecules

Biomaterials Science Center - University of Basel

Founded in 2007, this center at the University of Basel addresses major medical challenges, including cardiovascular and musculoskeletal diseases, cancer, incontinence, and caries.

Considering the importance of these issues, since 2005, professors and specialists related to biomaterials in the faculties of pharmacy, medicine, dentistry, Biochemistry-Biophysics Research Center (IBB), Faculty of Materials and Metallurgy, Faculty of Chemistry and Faculty of Veterinary Medicine at Tehran University and Tehran University of Medical Sciences, have spontaneously come together and established the BRC Biomaterial Research Center to coordinate and implement educational and research affairs related to biomaterials, and have achieved valuable achievements so far. In continuation of these activities, the specialized field of pharmaceutical biomaterials was also established in 2010 with the permission of the Ministry of Health, which resulted in the recruitment and training of about 45 Ph.D. students in 12 admission courses at Tehran Faculty of Pharmacy and the graduation of 18 students by 2003, as well as the implementation of several specialized courses for each of the faculties of pharmacy in Tabriz, Zanjan and Kermanshah.

Graduates' job positions:

Graduates of this field will play a role in production, and monitoring activities in the field of biopharmaceuticals, which are widely used and applied in various fields of medical sciences today, from diagnosis to monitoring and treatment of diseases. Also, in accordance with the stipulation of Part B, Clause 11, Article 1 of the Law on the Organization and Duties of the Ministry of Health, Treatment and Medical Education, approved by the Islamic Consultative Assembly on 03/03/1367, regarding the supervision of these products, in order to protect the health of the community, they will work as specialists in the educational, research and technological fields of this field. Also, working in the field of biopharmaceuticals industry in the form of Knowledge enterprise companies is another important position for graduates of this field.

The Philosophy of this field (Values and beliefs):

Based on the provisions of paragraphs 11, 12, 13 and 17 of the Law on the Organization and Duties of the Ministry of Health and Medical Education and Note 2, Article 3, Note 5, Article 13, Note 2, Article 14 and Articles 24 to 25 of the Law on Regulations on Medical and

Pharmaceutical Affairs and Food and Beverages, since 1955, monitoring the quality of these products has been mandatory by the Ministry of Health. With the increasing use of these products in the prevention, monitoring and treatment of diseases; as well as improving the quality of human daily life, monitoring the quality and the paths and strategies for ensuring the quality of these products in various production processes is a matter that, in addition to preserving and ensuring the health of the society, will generate wealth and consolidate the scientific position of the country. The divine principles and religious values emanating from the glorious Islamic Revolution of Iran, the existential value of man and his moral beliefs are an integral part of education in the fields of pharmacy, especially the field of biopharmaceuticals. The values and beliefs of the field of biopharmaceuticals are centered on health and increasing the quality of life of patients with acute and chronic disorders. The philosophy of the field of pharmaceutical biomaterial relies on education and acquisition of professional skills to preserve life and ensure and promote human health and dignity. In this regard, to provide effective and efficient conditions, emphasizing social justice and equality of humans, recognizing and overcoming difficulties, utilizing innovative experiences and research, and emphasizing the use of existing national resources, along with the use of the latest and most advanced science and technology, are the foundations of the establishment of this field.

In developing this program, the following values are emphasized:

- Improving the quality of human life by benefiting from the convergence of sciences
- Producing products that are useful in maintaining and promoting human health
- Applying fast, accurate, efficient, and cost-effective methods in diagnosing diseases
- Relying on priorities and utilizing the country's actual and potential facilities
- Moving towards ensuring the country's independence in the field of science and technology production
- Giving importance to understanding the phenomena of creation and creative thinking
- Validating new ideas and turning them into products
- Adhering to Islamic and professional ethics
- Stabilization the relationship between universities and industry
- Translating the bioscience of pharmaceuticals from the laboratory to the clinic
- Developing a Knowledge enterprise economy

Outlook:

With the increasing expansion of the production and supply of biopharmaceuticals, the critical role of quality assurance and monitoring of these products has become increasingly important compared to the past. It is expected that by scientific communication between experts in both the scientific fields of pharmaceutical biomaterial and pharmaceuticals and conducting applied research related to the biopharmaceutical industry and other related topics, it will be possible to accelerate the field of pharmaceutical biomaterial technology and meet the needs of society and industry.

Mission:

The mission of the field of pharmaceutical biomaterials at the Ph.D. level is to train capable and committed human resources who, by evaluating the needs, conduct research and produce science and convert up-to-date knowledge into technology. Utilizing the knowledge of pharmaceutical biomaterial in the direction of processing technology-based products and services for treatment and diagnosis in medicine and pharmacy, and ultimately supervising and monitoring the quality of manufactured and imported products, is the main mission of graduates of this field.

General goals:

- Educating graduates acquaint with interdisciplinary activities with a convergent approach to solving health challenges according to the Science, Technology, Engineering and Mathematics (STEM) model
- Self-sufficiency in the field of biopharmaceuticals by producing them in Knowledge enterprise companies
- Standardization of imported and manufactured biopharmaceuticals

Main goals:

- To educate and train specialists in the field of pharmaceutical biomaterial for the qualitative assessment of biopharmaceuticals, their production and processing
- To communicate with related industries
- To create convergence between specialists in the fields of technology, engineering and medical sciences to meet the needs of the health sector in the field of biopharmaceuticals

The main roles of this field graduates:

-Educational -Research - Design and production - Service - Consulting

Expected Competencies and Skills for Graduates

A: Expected Basic Competencies (General Competencies)

The general competencies expected for graduates of this level are:

- Communication - interaction skills
- Learning to research and write scientific articles
- Critical thinking and problem-solving skills
- Evidence-based management skills (policy-making, planning, organizing, monitoring, supervision and control, evaluation)
- Professionalism

B: Expected specific competencies (Special Competencies)

Special Competencies	professional duty Description	Related course codes
Educational	- Teaching general and specialized courses in biopharmaceuticals related to various sciences such as biology, nanotechnology, tissue engineering and diagnostic-therapeutic imaging, and applied cellular and regenerative science. - Designing drug release systems focusing on biopharmaceuticals, gene therapy and diagnostics related to mechatronics for use in the fields of diagnostics, therapy and separation, medical equipment, etc. at various levels of education - Preparing specialized educational texts such as translating, writing books related to pharmaceutical biomaterial, and developing standards related to pharmaceutical biomaterial	02,11,12,14,15
Research	- Research in research centers related to pharmaceutical biomaterial in the fields of tissue engineering, regenerative medicine, artificial organs, diagnostic-therapeutic systems and microfluidic systems and the use of 3D printers - Conducting joint research with knowledge-based companies with biopharmaceuticals and research experts related to biopharmaceuticals, companies producing pharmaceutical food and medical equipment in order to solve the problems of these industries in the fields related to biopharmaceuticals. - Research in the field of standardization and novel, and more accurate methods of production and quality control of drugs and food and medical equipment related to biopharmaceuticals and presenting these methods to control laboratories	9, 10, 12
Design and production	- Creating Knowledge enterprise companies related to biopharmaceuticals for entrepreneurship for graduates of this field - Innovation in the design, production and control of new biomaterials, including medical implants, such as orthopedic, cardiac and ophthalmic implants - Pilot design and creation of a basis for manufacturing and biological studies	02, 09, 10, 19, 24
Service	- Launching, monitoring and precise control of the various stages of biopharmaceutical production, including both manufactured and imported biopharmaceuticals - Developing regulatory standards related to biopharmaceuticals - Designing, constructing and launching various systems in the field of biopharmaceuticals - Empowering the country's required infrastructure in the field of biopharmaceutical knowledge	14, 15, 19
Consulting	- Consulting on research and industrial projects in the field of controlling affairs related to biopharmaceuticals - Consulting on the correct methods of controlling different types of biopharmaceuticals - Offering advice to biopharmaceutical quality control laboratories and quality control centers - Consulting on the standardization of biopharmaceuticals and cooperation with related ministries and institutions	02, 14, 15, 19

C. Expected Procedural Skills:

- Design and manufacture of biopharmaceuticals

- Control and evaluation of biopharmaceuticals

- Setting up systems related to biopharmaceuticals

- Standardization and regulation of biopharmaceuticals

Educational Strategies:

- This program is based on the following strategies:
- Task-based Education
- Student-centered and teacher-centered education
- Lab-based Education
- The need to use a blended learning management system (LMS) for blended learning as well as online platforms should be considered

Educational methods and techniques:

The following educational methods and techniques will be mainly used in this course:

- Various intra-departmental, inter-departmental, hospital, industrial, interdisciplinary, inter-university conferences and seminars
- Discussion in small groups - educational workshops - journal clubs and book reading groups
- Use of simulation techniques and distance learning according to facilities and artificial intelligence
- Participation in the education of lower levels
- Self-education, self-study
- Other educational methods and techniques according to educational needs and goals

Ethical expectations from students:

- observe the legal charter (1) of patients exactly
- observe the regulations related to the protection and safety of patients, staff and the work environment exactly (These regulations are developed by the relevant educational group)
- Observe the regulations related to the Dress Code (2)
- observe the relevant ethical regulations (3) while working with animals (Professionalism)
- Protect the resources and equipment that they work with in any conditions
- Respect professors, staff, fellow courses and other students and participate in creating a friendly and respectful atmosphere in the work environment.
- Respect to social and professional ethics in program reviews
- Respect to research ethics in conducting research related to the field
    - Items 1, 2, 3 are given in the appendices of this program

Student Assessment:

A - Students will be assessed using the following methods:

-Written Oral Interactive computer test Project-based assessment

-Portfolio assessment includes log book assessment, test results, articles, encouragement and reminders, certificates of work done, etc.

B - Assessment frequency:

*Intra-group tests are in possession to the educational group.

During the course, students pass written tests related to the courses and the comprehensive board exam and submit progress reports related to their thesis. Students are also required to complete practical courses in laboratories related to the Biomaterials group. (Lab rotation)

Chapter Two

Minimum Requirements for the Doctoral Program in Pharmaceutical Biomaterials (Ph.D.)

Minimum required faculty:

A - Full-time permanent faculty members based on the approval of the Council for the Development of Medical Sciences Universities with specializations in pharmaceutical biomaterial, biomaterials, pharmaceutics, clinical pharmacy and tissue engineering

B - Required supporting specializations:

Educational departments of pharmaceutics, medicinal chemistry, pharmaceutical/medical nanotechnology, tissue engineering, biotechnology, biophysics and biochemistry, metallurgy, polymer, artificial intelligence, mechatronics, clinical pharmacy, toxicology and pharmacology

Trained staff required to implement the program

At least one laboratory expert with qualifications and experience in laboratory equipment for manufacturing and characterizing biopharmaceuticals

At least one laboratory expert with qualifications and experience in laboratory work on cell culture and related tests

General educational spaces and facilities required

-Classrooms - Student rooms - Education archives

-Independent laboratory - Library - Internet with appropriate speed

-Conference hall - Professors' room - Computer room

- Dedicated educational website of the educational department

Required dedicated spaces and areas:

- Pharmaceutical biomaterials manufacturing laboratory
- Biomaterials characterization laboratory
- Physical and chemical control laboratory
- Medicinal chemistry laboratory
- Pharmaceutics laboratory
- Cell culture laboratory
- Quality control laboratory
- Access to animal room and animal house
- In order to use the integrated management system (LMS) and online platforms, computer and electronic equipment is required.

Populations or samples required:

- Laboratory samples obtained from patients
- Laboratory animals as disease models

- Biomaterial samples prepared in the laboratory

Major specialized equipment required:

- At least 4 specialized devices required for biomaterial manufacturing
- At least 2 specialized devices for biomaterial characterization

Major specialized equipment required:

- Chromatography devices (such as (HPLC
- UV spectrophotometer
- IR device
- Thermal analysis devices (DSC)
- Dissolution tester
- refrigerated and high-speed Centrifuge
- Ultrasonic bath
- Light and invert microscopes
- Eliza reader
- Fluorescence microscope
- Nitrogen tank
- Cell culture chamber
- Freezer -70
- Electrospinning device
- Conventional incubator and shaker incubator and CO2 incubator
- UV device
- Homogenizer (simple and for nano studies)
- 3D printer
- Particle size analyzer Nanosizer, Zetasizer
- Freeze dryer
- Electron microscope and GPC
- Specialized equipment for the construction and evaluation of microfluidic systems

Chapter Three

Course Specifications and Syllabi Educational Program for the Field of Pharmaceutical Biomaterials at the Doctor of Philosophy (Ph.D.) Level

Course Specifications 1 - Course Name: Doctor of Philosophy (Ph.D.) in Pharmaceutical Biomaterials

Duration and Structure: Determined according to the educational regulations for the Doctor of Philosophy (Ph.D.) degree approved by the Supreme Council for Medical Sciences Planning.

Total Course Units: The total number of course units in this program is 42, as follows:

Unit Type	Number of Units
Core Courses (Compulsory)	16 Units
Non-core Courses (Elective)	4 Units
Dissertation	22 Units
Total	**42 Units**

Table A - Deficiency or Compensatory Courses for the Ph.D. Program in Pharmaceutical Biomaterials

Code	Course Name	Number of credits			Number of hours			Prerequisite/ Requisite
		Total	Theory	Practical	Total	Theory	Practical	
01	Principles of Biopharmaceutics & Pharmacokinetics	3	3	-	51	51	-	-
02	Novel Drug Delivery Systems	3	3	-	51	51	-	-
03	Physical Pharmacy I *	2	2	-	34	34	-	-
04	Physical Pharmacy II *	2	2	-	34	34	-	-
05	Cellular & Molecular Biology	3	3	-	51	51	-	-
06	Medical Information Systems	1	0.5	0.5	26	9	17	-
07	Principles of Disaster & Hazard Risk Management **	2	1	1	17	34	51	-
08	Polymer Chemistry	2	2	-	34	34	2	-
09	Biostatistics	2	1	1	17	34	-	-
	Total	**20**						

- Students must take all or some of the deficiency/compensatory courses in Table A based on the diagnosis of the relevant academic department and approval of the University's Postgraduate Council.

*Selection of Physical Pharmacy I or Physical Pharmacy II from the general pharmaceutics courses of the Faculty of Pharmacy is determined by the Pharmaceutical Biomaterials department based on the academic level of the Ph.D. student.

**Taking these courses (Medical Information Systems & Disaster Management) is mandatory for all students who have not previously passed them.

Table B - Core (Compulsory) Courses for the Ph.D. Program in Pharmaceutical Biomaterials

Code	Course Name	Number of credits			Number of hours			Prerequisite/ Requisite
		Total	Theory	Practical	Total	Theory	Practical	
10	Pharmaceutical Biomaterials I	3	2	1	68	34	34	01,02,03,04
11	Pharmaceutical Biomaterials II	3	2	1	68	34	34	10
12	Biocompatibility	2	1	1	51	17	34	-
13	Tissue Engineering & Bio-scaffolds	3	2	1	68	34	34	-
14	Seminar	1	1	-	17	17	-	-
15	Advanced Methods of Identification & Instrumental Analysis	3	2	1	68	34	34	-
16	Principles of Standardization & Safety of Biomaterials	1	1	-	17	17	-	-
17	Dissertation	22	-	-	-	-	-	-
	Total	**38**						

Table C: Non-core (Elective) Courses for the Ph.D. Program in Pharmaceutical Biomaterials

Code	Course Name	Number of credits				Number of hours				Prerequisite / Corequisite
		Total	Theory	Practical	Internship	Total	Theory	Practical	Internship	
18	Principles of Innovation Economics & Intellectual Property	1	1	-	-	17	17	-	-	-
19	Artificial Intelligence & Machine Learning	3	2	1	-	68	34	34	34	-
20	Internship in Knowledge-Based Companies, Biomaterials Research Centers, or Clinical Centers	1	-	-	1	51	-	-	51	-
21	Nanotoxicology	2	2	-	-	34	34	-	-	-
22	Peptide & Protein Chemistry	2	2	-	-	34	34	-	-	-
23	Medical Ethics in Pharmaceutical Biomaterials	1	1	-	-	17	17	-	-	-
24	Novel Techniques in Smart Drug Delivery	3	2	1	-	68	34	34	-	-
	Total Available	**13**								

***** Students must take 4 units from the elective courses in Table C, based on their dissertation topic, supervisor's opinion, and the emphasis of the academic department.

Required Educational Workshops: (Students must complete 2 workshops from the list below):

1. Chip Design Workshop via Soft Photolithography
2. Microfluidic System Design
3. Fiber Design Workshop via Electrospinning
4. Cell Culture Workshop
5. Experimental Design Workshop

6. Analysis Systems Workshop
7. HPLC
8. FT-IR
9. SEM
10. TEM
11. NMR
12. AFM
13. GC
14. Cytotoxicity Workshop
15. Stem Cell Culture
16. Peptide Design, Synthesis, and Analysis

Course name: Principles of biopharmaceutical & Pharmacokinetics **Course Code:** 01

Prerequisite/Corequisite: None

Units: 3 Units

Unit Type: Theory

General Objectives:

- Familiarity with the fate of dosage forms in the body and the factors affecting it (physicochemical properties, effect of formulation changes, physiological properties: effect of age, sex, disease, genetics, and nutrition).

Specific Course Objectives: At the end of the course, the student is expected to be able to:

Know the structure of membranes and transport mechanisms.

Identify factors affecting transport.

Know different pharmacokinetic models.

Determine pharmacokinetic parameters.

Course Description:

Pharmacokinetics examines the behavior of drugs in the body through the processes of absorption, distribution, metabolism, and excretion. Drug interactions and interference in treatment based on pharmacokinetic models are among the most important principles discussed in this course.

Syllabus (51 Hours Theory):

Introduction and basic concepts

Absorption and membrane transport mechanisms

Physicochemical factors affecting absorption

Distribution phenomenon and factors affecting it

Clearance and ER (Extraction Ratio)

Renal and biliary excretion

One-compartment intravenous model

One-compartment extravascular model

Non-linear pharmacokinetics

Bioavailability and bioequivalence of drugs 1

Bioavailability and bioequivalence of drugs 2

Two-compartment model and problem solving

Multiple dosing administration

Calculation of kinetic parameters from urinary data

Factors affecting pharmacokinetic variations

Main Course Resources:

Applied Biopharmaceutics and Pharmacokinetics. Leon Shargel and Andrew.

Biopharmaceutics and Clinical Pharmacokinetics. Milo Gibaldi.

Clinical Pharmacokinetics. Rowland and Tozer.

- Related Journals

Teaching Methods:

Explaining the objectives of each topic, using educational slides, involving students in class discussions, referring to reference books for deeper understanding, solving exercises, and using educational films and slides.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam

Course name: Novel Drug Delivery Systems **Course Code:** 02

Prerequisite/Corequisite: None

Units: 3 Units

Unit Type: Theory

General Objectives: To familiarize the student with novel systems in drug design and new methods in drug delivery.

Course Description: Targeted drug delivery to the site of action with high efficiency.

Syllabus (51 Hours Theory):

1. Mechanisms of biomaterial release.
2. Controlled release systems for releasing biological substances/drugs in the body via transdermal patch, nasal, ophthalmic, oral, subcutaneous, GIT (Gastrointestinal Tract), injection, peritoneal routes, and various types of controlled drug release systems.
3. Biodegradable subcutaneous systems.
4. Targeted release of biomaterials in the human brain.
5. Controlled release for neural networks.
6. Targeted release of biological materials in bone.
7. Controlled release systems for other body organs (specific organ: heart, lung, eye, external surface of vessels (vascular), digestive system).
8. Materials used in preparing controlled release systems.
9. Micro and nano coatings (encapsulation).
10. Nanocapsules and manufacturing methods (solid lipid particles, synthetic and natural polymeric particles, metallic and magnetic particles).
11. Nanocapsules and preparation methods (liposomes, polymersomes, polymers).
12. Targeted nanoparticles and applications.
13. Smart systems.

Main Course Resources:

1. Biopharmaceutics and Pharmacokinetics. Notari, R.E., Marcel Dekker, latest edition.
2. Novel Drug Delivery Systems. Y. W. Chien (editor), Marcel Dekker Inc, latest edition.
3. Colloidal Drug Delivery Systems. J. Kreuter (editor), Marcel Dekker Inc, latest edition.
4. Therapeutic Peptides and Proteins: Formulation, Processing and Delivery Systems. A. K. Banga, CRC Press, latest edition.
5. Controlled Drug Delivery: Fundamentals and applications. J. R. Robinson and V. H. Lee

(editors), Marcel Dekker Inc, latest edition.
6. Microencapsulation Systems for the Delivery of Proteins and Vaccines. S. Cohen and H. Bernstein (editors), Marcel Dekker Inc, latest edition.
7. Drug Delivery and Targeting. A. M. Hillery, A. W. Lloyd and J. Swarbrick (editors), Taylor & Francis, latest edition.
8. Modified-Release Drug Delivery Technology. M. J. Rathbone, J. Hadgraft and M. S. Roberts (editors), Marcel Dekker Inc, latest edition.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam

Course Name: Physical Pharmacy I **Course Code:** 03

Prerequisite/Corequisite: Mathematics

Units: 2 Units

Type: Theory

General Objectives:

- Familiarizing students with physicochemical principles and concepts in the formulation of dosage forms.
- Familiarizing students with chemical bonds, isotonic solutions, application of complex formation, phase equilibria, and liquid crystals.

Course Description:

This course discusses the physicochemical principles and concepts in drug manufacturing, as well as the physical laws related to drug preparation and formulation.

Syllabus (34 Hours Theory):

- Principles of preparing isotonic solutions and buffers.
- Factors affecting drug dissolution and solubility, and methods to increase dissolution rate.
- Effect of heat, polymorphism, etc., on formulation and drug stability.
- Different methods of isotonic adjustment and preparing buffer solutions.
- Importance of dissolution in drug formulation.
- Properties of non-electrolyte solutions and their application in pharmacy.
- Difference between ideal and real solutions.
- pH calculation.
- Concept of complexes and their types.
- Rheology and its role in pharmaceutical formulations - liquid, semi-solid, and solid products.

Main Course Resources:

1. Martin's Physical Pharmacy and Pharmaceutical Sciences. LWW, The latest edition.
2. Remington: The Science and Practice of Pharmacy. LWW, The latest edition.
3. Physicochemical Principles of Pharmacy. Attwood D, Florence AT, Pharmaceutical Press, The latest edition.
4. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Churchill Livingstone, The latest edition.

Student Evaluation Method:

Midterm exam (essay-multiple choice), Final exam (essay-multiple choice), Exercise solving.

Course Name: Physical Pharmacy II **Course Code:** 04

Prerequisite/Corequisite: -

Units: 2 Units

Unit Type: Theory

General Objectives:

Familiarizing students with the physical and chemical principles related to the design of pharmaceutical products and studying the mechanisms of drug preparation and manufacturing.

Course Description:

Introduction to designing biomaterials in various dosage forms, understanding the main mechanisms of their design and processing.

Syllabus (34 Hours Theory):

Mechanistic properties of biomaterials for designing dosage forms are discussed:

a) Drug stability including:
- Stability study techniques.
- Investigating half-life and drug expiration date.

b) Role of diffusion and dissolution in pharmaceutical formulations.
c) Interfacial phenomena, surface phenomena, and colloidal systems; investigating problems arising from them in the stability and bioavailability of dosage forms.
d) Application of thermodynamic principles in solving pharmaceutical formulation problems.
e) Role of micromeritics in drug manufacturing and bioavailability.
f) Investigating protein binding of drugs in therapeutic targets.
g) Role of liquid crystals and investigating problems arising from them in pharmacy.
h) Physics of polymers in pharmacy.

Main Course Resources:

1. Martin's Physical Pharmacy and Pharmaceutical Sciences. LWW, latest edition.
2. Physical Pharmacy. Ridgway K, Shotton E, Oxford University Press, latest edition.
3. Physicochemical Principles of Pharmacy. Florence AT, Attwood D, Pharmaceutical Press, latest edition.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam

Course Name: Cellular & Molecular biology **Course Code:** 05

Prerequisite/Corequisite: None

Units: 3 Units

Unit Type: Theory

General Objectives:

Study of cell structure and molecular biology.

Course Description:

Investigation of the biological and molecular structure of the living cell.

Syllabus (51 Hours Theory):

1. Introduction to cell biology.
2. Cell biology: organelles and their functions.
3. Structure and function of the cell.
4. Structure and function of carbohydrates.
5. Structure and function of proteins.
6. Structure and function of nucleic acids.
7. Structure and function of lipids.
8. Cell membrane and membrane transport mechanisms.
9. Enzymes and enzymology.
10. Gene expression: replication, transcription, and translation.
11. Genetic engineering and DNA manipulation.
12. Bioenergetics.
13. Stem cells.
14. Cellular and molecular mechanisms of cancer.

Main Course Resources:

1. Essentials of Molecular Biology. Malacinski GM, Freifelder D, Jones and Bartlett, The latest edition.
2. Essential Cell Biology. Alberts B et al., Taylor and Francis Group, The latest edition.
3. Molecular Cell Biology. Lodish H et al., W. H. Freeman, The latest edition.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam.

Course Name: Medical Information Systems **Course Code:** 06

Prerequisite/Corequisite: None

Units: 1

Unit Type: (0.5 Theory - 0.5 Practical)

General Objectives:

At the end of this course, the student should be able to identify the different components of a personal computer and know their functions, be familiar with the Windows operating system, install and troubleshoot it, and learn to work with important application programs. They should also be able to use library templates and different search methods in important databases in their field of study and become familiar with the library services of their university. Another objective is familiarity with famous internet browsers so that the student can work with search engines and become familiar with well-known and useful informational websites in their field. Finally, the student should be able to create and use email for sending and receiving messages and files.

Course Description:

In this course, the student becomes familiar with different components of a personal computer, the Windows operating system, the internet, important websites, email, and databases to practically use the computer and its facilities for study and research in their field.

Syllabus (9 Hours Theory - 17 Hours Practical)**:**

*Familiarity with the personal computer:
- Identifying different hardware components and peripherals.
- Function and importance of each hardware component and peripheral.

*Familiarity with and launching the Windows operating system:
- History of advanced operating systems, especially Windows.
- Capabilities and features of the Windows OS.
- How to use Windows Help.
- Familiarity with important Windows applications.

*Familiarity with important databases and applied scientific software in the field of study:
- Introduction and terminology of information retrieval.
- Familiarity with reference book software for the field on CD-ROM and how to use them.
- Familiarity with databases such as Medline, Embase, Biological Abstracts, etc., and how to search them.
- Familiarity with full-text electronic journals available on CD-ROM and search methods.

*Familiarity with the Internet:
- Familiarity with information networks.
- Familiarity with important internet browsers and learning their various aspects.
- Learning how to configure the internet browser for network connection.
- How to work and search with important search engines.
- Familiarity with several famous and important websites in the field of study.

Main Course Resources:

1. Finding Information in Science, Technology and Medicine. Lambert J, Taylor & Francis, The latest edition.
2. Information Technology Solutions for Healthcare. Zieliński K et al., Springer, The latest edition.

Student Evaluation Method:

- Cognitive domain: Student evaluation is done mid-term and end-term through essay questions.
- Psychomotor domain: Practical test of the student's skill in using the computer, Windows OS, and internet search using a checklist.

Course Name: Principles of Disaster & Hazard Risk Management **Course code:** 07

Prerequisite/Corequisite: None

Units: 2 Units

Unit Type: (1 Theory - 1 Practical)

General Course Objective:

To familiarize students with the concepts and fundamentals of disaster risk management, including understanding the risk management cycle, concepts and structure of risk management, principles of management and planning in the health sector during the mitigation, preparedness, response, and recovery phases of disasters and emergencies, and basic principles of self-help and mutual aid.

Course Description:

In this course, the student, while becoming familiar with the common terminology of disaster risk management, will learn vital practical skills such as basic CPR, triage, etc.

Syllabus: (17 Hours Theory - 34 Hours Practical)

A) Theory (17 Hours)**:**

- ✓ Introduction to general concepts, terminology, importance, and necessity of disaster and emergency management.
- ✓ Familiarity with natural and man-made hazards globally and in Iran.
- ✓ Familiarity with disaster prevention methods.
- ✓ Familiarity with methods for enhancing preparedness for effective response to disasters and emergencies.
- ✓ Familiarity with the psychological effects of disasters and psychosocial support.
- ✓ Familiarity with post-disaster recovery and returning to a better state than before.
- ✓ Familiarity with the Incident Command System (ICS) and its functions.
- ✓ Familiarity with national laws and documents on disaster and emergency management.

B) Practical (34 Hours)**:**

- ✓ Performing basic CPR (one and two-person), using a mannequin, working with an Automated External Defibrillator (AED).
- ✓ Participating in exercises (tabletop, fire extinguishing...).
- ✓ Familiarity with performing basic triage.
- ✓ Risk asses

Course Name: Polymer Chemistry **Course Code:** 08

Prerequisite/Corequisite: None

Units: 2 Units

Type: Theory

General Objectives:

Familiarity with the basics of chemistry, properties, preparation methods, and applications of polymers.

Course Description:

Investigation of the structure and physicochemical properties of polymers.

Syllabus (34 Hours Theory)**:**

- Introduction: Historical background, definitions, classification, role of polymers in technological advancement.
- Methods for preparing synthetic polymers: Radical polymerization, cationic polymerization, anionic polymerization, polymerization by convergent initiators, types of initiators.
- Investigation of the mechanism and kinetics of radical, anionic, and cationic polymerization reactions.
- Study of polymer structure: Spatial arrangement of polymer chains, molecular weight, methods for determining molecular weight, and physical properties of polymers.
- Natural polymers: Natural rubber, cellulose and its derivatives, proteins, rubbers.
- Processing of plastics and rubbers.

Main Course Resources:

1. Principles of Polymerization. G. Odian, John Wiley & Sons, The latest edition.
2. Contemporary Polymer Chemistry. Allcock H, Lampe F, Mark J, Prentice Hall, The latest edition.
3. Polymer Chemistry. Hiemenz PC, Lodge TP, CRC Press, The latest edition.
4. Polymer Chemistry: An Introduction. Stevens MP, Oxford University Press, The latest edition.
5. Polymer Science and Technology. Fried JR, Prentice Hall, The latest edition.
6. Polymer Macrogalleria: https://www.google.com/search?q=http://www.pslc.ws/macrog/

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam

Course Name: Biostatistics **Course Code:** 09

Prerequisite: None

Units: 2 Units

Unit Type: (1 Theory - 1 Practical)

General Objectives:

To familiarize students with various advanced statistical tests and methods used for analyzing findings from basic and applied research related to the field of Pharmaceutical Biomaterials, and their applications and use cases.

Course Description:

This course will discuss various statistical tests related to comparing proportions, examining correlations in nominal data, analysis of quantitative data, correlation of quantitative data, linear and non-linear regression, selecting the best model for experimental data, analysis of covariance (ANCOVA), and factorial design analysis, from the perspective of their application in interpreting results from studies related to the field of Pharmaceutical Biomaterials.

Syllabus (17 Hours Theory - 34 Hours Practical):

1. Statistical tests for comparing proportions:
- Test for difference between a proportion and a hypothesized proportion (binomial).
- Test for difference between a proportion and a hypothesized proportion (multinomial).
- Test for difference between two proportions (2x2 contingency tables, Fisher's exact test...).
- Test for difference in proportions in paired or dependent samples (McNemar test).
- Test for examining proportions in paired observations (more than twice) (Cochran's Q test).

2. Examining correlation in nominal data:
- In 2x2 contingency tables.
- Among nominal variables with more than two levels.

3. Analysis of quantitative data:
- Checking for normality of distribution shape.
- Test for difference between the median and a hypothesized number.
- Test for difference between the mean and a hypothesized number.
- Examining quantitative data in paired observations.
- Examining quantitative data in two unpaired (independent) samples.
- Examining quantitative traits in several groups (repeated and non-repeated observations) (ANOVA, Dunnett, Newman-Keuls, Tukey HSD, Kruskal-Wallis, Friedman tests).

5. Correlation of quantitative data:
- Pearson correlation coefficient.
- Spearman correlation coefficient.

6. Linear regression:

- Analysis of residuals.
- Checking for equality of variances (Levene's test).
- Checking for linearity of data.

7. Non-linear regression:
- Various parameters and types of empirical models.
- Selecting the best model for analyzing experimental data.

8. Analysis of Covariance (ANCOVA) test.
9. Factorial analysis using Factorial design, two-way ANOVA test.

Main Course Resources:

1. Statistics for Health Professionals. Shott S, W.B. Saunders Co, The latest edition.
2. Practical Statistics for Field Biology. Fowler J, Cohen L, Jarvis P, John Wiley and Sons Ltd., The latest edition.
3. Statistical Methods in Medical Research. Armitage P, Berry G, Matthews JNS, Blackwell Science Inc., The latest edition.
4. Biostatistics: A Foundation for Analysis in the Health Sciences. Daniel WW, Cross CL (or Henderson D?), John Wiley and Sons Inc., The latest edition.
5. Basic Statistics and Pharmaceutical Statistical Applications. De Muth JE, Marcel Dekker Inc., The latest edition.
6. Pharmaceutical Statistics: Practical and Clinical Applications. Bolton S, Bon C, Marcel Dekker Inc., The latest edition.
7. PDQ Statistics. Norman GR, Streiner DL, Mosby-Year Book, The latest edition.
8. Specialized articles related to the various topics discussed.

Student Evaluation Method:

Midterm exam (multiple choice & essay), course projects, final exam (multiple choice & essay).

Course Name: Pharmaceutical Biomaterials I **Course Code:** 10

Prerequisite/Corequisite: Physical Pharmacy I & II, Principles of Biopharmaceutics & Pharmacokinetics, Novel Drug Delivery Systems

Units: 3 Units

Unit Type: 2 Theory - 1 Practical

General Objectives:

- Familiarizing students with polymeric, metallic, ceramic, and composite biomaterials.
- Familiarizing students with the general principles of processing pharmaceutical biomaterials.
- Familiarizing students with nano pharmaceutical biomaterials and their manufacturing methods.
- Familiarizing students with the application of biomaterials in drug delivery systems and gene therapy.

Course Description:

This course is taught due to the increasing application of biomaterials in medical and biological sciences and the growing interest of the pharmaceutical industry in producing biomaterials.

Syllabus (34 Hours Theory - 34 Hours Practical):

- Introduction to pharmaceutical biomaterials.
- Metallic biomaterials and their applications.
- Polymeric biomaterials and their applications.
- Ceramic biomaterials and their applications.
- Composite biomaterials and their applications.
- Implants and their applications.
- Synthesis and processing of nanobiomaterials.
- Rheology of biomaterials.
- Surface modification of biomaterials.
- Biodegradability.
- Novel methods in biomaterial processing.

Main Course Resources:

1. Biomaterials Science and Technology: Fundamentals and Developments. 2019 by Taylor & Francis Group, LLC.
2. Biomaterials and Materials for Medicine: Innovations in Research, Devices, and Applications. Edited by Jingan Li, 2022 by CRC Press.
3. Articles and other related books (latest editions).

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam.

Course Name: Pharmaceutical Biomaterials II **Course Code:** 11

Prerequisite/Corequisite: Pharmaceutical Biomaterials I

Units: 3 Units

Unit Type: (2 Theory - 1 Practical)

General Objectives:

Familiarizing students with the design and application of biomaterials in biological systems.

Course Description:

This course is taught due to the increasing application of biomaterials in medical and biological sciences and the growing interest of the pharmaceutical industry in producing biomaterials.

Syllabus (34 Hours Theory - 34 Hours Practical):

1. Types of nanomaterials and their properties.
2. Drug/Gene delivery systems - an introduction.
3. Organ-on-a-chip, Lab-on-a-chip, Cell-on-a-chip.
4. Tissue/organ targeted delivery systems (e.g., brain, bone marrow...).
5. Theranostics.
6. Stimuli-sensitive systems.
7. Biosensors.
8. Protein immobilization / Protein-peptide formulations.
9. Active and passive targeting.
10. Therapeutic cells / Cell conjugates / Cell-based delivery systems.
11. Biomaterials quality control and regulatory criteria.

Main Course Resources:

1. An Introduction to Biomaterials. Scott A. Guelcher, William R. Wagner, CRC Press, The latest edition.
2. Biomaterials Science: An Introduction to Materials in Medicine. Ratner BD, Hoffman AS, Schoen FJ, Lemons JE, Academic Press, The latest edition.
3. Biomaterials: The Intersection of Biology and Materials Science. Wong JY, Bronzino JD, CRC Press, The latest edition.
4. Biomaterials. Bhat SV, Springer, The latest edition.
5. Biomaterials, Medical Devices and Tissue Engineering: An Integrated Approach. Silver FH, Christiansen DL, Springer, latest edition.
6. Handbook of Biomaterials Evaluation: Scientific, Technical And Clinical Testing Of Implant Materials. Von Recum AF (editor), CRC press, the latest edition.
7. Nanoscopic Materials: Size-Dependent Phenomena. Roduner E, Royal Society of Chemistry, the latest edition.
8. Nanostructures and Nanomaterials: Synthesis, Properties and Applications. Cao G, World

Scientific, the latest edition.
9. Novel Drug Delivery and Its Therapeutic Application. Prescott LF, Nimmo WS (editors), Wiley, The latest edition.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam.

Course Name: Biocompatibility **Course Code:** 12

Prerequisite/Corequisite: None

Units: 2 Units

Unit Type: (1 Theory - 1 Practical)

General Objectives:

Considering the advancements in pharmaceutical science at the molecular level and the foundational role of genetics in drug manufacturing, this course provides necessary basic information to students.

Course Description:

Study of adapting biomaterial characteristics to in vivo conditions (tissue, living cell).

Syllabus (17 Hours Theory - 34 Hours Practical)**:**

- Familiarity with methods for extraction and separation of biological molecules.
- Familiarity with PCR.
- Familiarity with ELISA.
- Familiarity with DNA Cloning and genetic engineering.
- Familiarity with flow cytometry.
- Molecular immunology.
- Structure and types of antibodies.
- Types of mutations.
- Methods for creating mutants.
- Familiarity with teratogens, carcinogens, and mutagens.
- Gene expression regulation in prokaryotes and eukaryotes.
- Molecular biology of pathogenicity of microorganisms (bacteria, fungi, parasites, phages).
- Familiarity with different methods of combating cancer through pharmacokinetic and pharmacodynamic interventions.

Main Course Resources:

Molecular Biology and Biotechnology. Walker J M, Gingold E B, Royal Society of Chemistry, latest edition.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam.

Course Name: Tissue Engineering & Bio-scaffolds **Course Code:** 13

Prerequisite/Corequisite: None

Units: 3 Units

Unit Type: (2 Theory - 1 Practical)

General Objectives: Familiarity with scaffold construction and how to culture and proliferate cells within them.

Course Description:

Tissue engineering requires familiarity and mastery of two specialties: materials and cell culture. This course investigates the principles of preparing various scaffolds from different biomaterials and how to culture and proliferate cells in them.

Syllabus (34 Hours Theory - 34 Hours Practical)**:**

- Fundamentals of histology.
- Fundamentals of cell growth and differentiation and principles of tissue culture.
- Dynamics of cell-environment interaction in relation to tissue engineering.
- Biomaterials in tissue engineering.
- Techniques for scaffold design and fabrication (3D printing...).
- Animal cell culture and the role of growth factors.
- Sterilization of tissue scaffolds.
- Targeted control of cell differentiation using physicochemical stimuli.
- Application of stem cells in tissue engineering.
- Regenerative medicine (skin, bone, bladder, spinal cord...).
- Drug delivery systems for tissue engineering.
- Immuno-Isolation.

Main Course Resources:

1. Tissue, Cell and Organ Engineering. Kumar C (editor), Wiley-VCH, The latest edition.
2. Principles of Tissue Engineering. Lanza R, Langer R, Vacanti J (editors), Academic Press, The latest edition.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam

Course Name: Seminar **Course Code:** 14

Prerequisite/Corequisite: None

Units: 1 Unit

Unit Type: Theory

General Objectives:

- Empowering students to present and lecture in scientific forums.
- Familiarizing students with current scientific topics in fields related to Pharmaceutical Biomaterials.

Course Description:

Enhancing students' skills in presenting and articulating scientific material.

Syllabus (17 Hours Theory):

- Novel drug delivery systems.
- New biomaterials and their applications.
- Smart drug delivery systems.
- Targeted therapy and new strategies.
- Gene delivery.
- Novel methods for manufacturing drug carriers.
- And related new scientific topics such as artificial intelligence, microfluidic systems, etc.

Main Course Resources:

The most up-to-date articles published in reputable scientific journals.

Student Evaluation Method:

Seminar presentation quality and content gathering, based on the opinions of the department's professors.

Course Name: Advanced Methods of Identification & Instrumental Analysis

Course Code: 15

Prerequisite/Corequisite: None

Units: 3 Units (2 Theory - 1 Practical)

Unit Type: Theory - Practical

General Objectives: To familiarize students with current identification and analytical tools in topics related to biomaterials.

Course Description: Today, determining species and their concentrations in target pharmaceutical materials is essential, which is done using various analytical tools. In addition, complex instruments for identifying biomaterials from micrometric and nonoperatic aspects are introduced to the student in this course.

Syllabus (34 Hours Theory - 34 Hours Practical)**:**

- Spectroscopic techniques in biomaterial identification.
- General principles of chromatography and purification methods (Liquid Chromatography and Gas Chromatography).
- Advanced NMR and its application in biomaterials.
- Advanced Mass Spectrometry and its application in biomaterials.
- Analysis of nanomaterials (SEM, TEM, AFM).
- Calorimetric techniques, surface analysis techniques, techniques based on medical imaging, flow cytometry, and confocal microscopy.
- Familiarity with microscopic devices: AFM, Confocal, and Fluorescence.
- Familiarity with measurement devices: LCMS, DLS, and HPLC.

Specific Objectives for 4 analytical devices: The following are taught for each of the 4 analytical instruments:

1- Familiarity with how the device works and its types.
2- Familiarity with preparing samples for the device.
3- Familiarity with factors for better measurement and imaging.
4- Familiarity with how to analyze data from the device and draw correct conclusions.

Main Course Resources:

1. Chromatography and Spectroscopy (Persian title), by Dr. Abbas Shafiee, Tehran University Press, latest edition.
2. Organic Spectroscopy: Principles and Applications. Jag Mohan, CRC Press, the latest edition.
3. Internet resources.

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, Q&A.

Summative: Written exam.

Course Name: Principles of Standardization & Safety of Biomaterials **Course Code:** 16

Prerequisite/Corequisite: None

Units: 1 Units

Unit Type: Theory

General Objectives:

Familiarity with qualitative and quantitative standards of biomaterials for their optimal design is among the topics of this course.

Course Description and Syllabus (17 Hours Theory)**:**

1) Introduction to standards and standardization.
- Standard organizations and how standards are developed.
- Standards for raw materials (Pharmacopeia).
- Standards for products (Pharmacopeia).
- Standards for pharmaceutical excipients.
- Standards for polymeric biomaterials.
- Standards for metallic biomaterials.
- Standards for ceramic biomaterials.
- Standards for processing and characterization of hydrogels.
- Standards for medical products (tissue engineering).
- Standards for biocompatibility.
- Definition of standard and its process.
- Who uses standards?
- Standard developers.
- FDA, ASTM, ISO.
- Standard development processes.
- Biocompatibility standards (in vitro, short-term and long-term in vivo tests).
- Quality control standards (in vitro, ex vivo, and in vivo tests).

Main Course Resources:

1. Research in Health Systems, WHO (World Health Organization).
2. Designing and Conducting Health System Research Projects. Varkevisser CM, Pathmanathan I, Brownlee A, KIT Publishers, The latest edition.

Student Evaluation Method: 50% Final exam (essay format), 50% Group work during the semester.

Course Name: Thesis **Course Code:** 17

Prerequisite/Corequisite: -

Units: 22 Units

General Objectives:

Designing and conducting a research project related to Pharmaceutical Biomaterials.

Course Description:

Students must conduct research according to the educational regulations for the Doctor of Philosophy (Ph.D.) degree approved by the Supreme Council for Medical Sciences Planning.

Student Evaluation Method:

In accordance with the educational regulations for the Doctor of Philosophy (Ph.D.) degree approved by the Supreme Council for Medical Sciences Planning.

Course Name: Principles of Economics, Innovation, and Intellectual Property

Course Code: 18

Prerequisite or Co-requisite: None

Number of Units: 1 Unit

Unit Type: Theoretical

General Educational Objectives: Training Residents in the Field of Biomaterials in the areas of research, development, innovation, idea commercialization, and enhancing their knowledge and skills.

Course Description:

- At the end of this course, the student will be familiar with the following topics.
- Theoretical foundations of research, development, and commercialization.
- Ethical considerations in the fields of research, development, and commercialization of pharmaceutical topics.
- Research and development indicators in local and national programs.
- Research and development approaches in pharmaceutical sciences in the coming decades (New Millennium).
- Information technology, research, and development.

Syllabus (17 Theoretical Hours):

- Principles of research and development
- Types of research and development methods
- Principles of idea commercialization
- Methods of idea commercialization
- Ethical considerations in research, development, and idea commercialization
- Incubation centers and science and technology parks
- Patent registration and its governing processes
- Global pharmaceutical market and development approaches of pharmaceutical companies
- Analysis of the Iranian pharmaceutical market
- Analysis of research and development policies of selected international companies

Main Course Resources:

1- Articles presented in each class session
2- Research and Development Management by Videokumar, latest edition

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, questions and answers

Summative: Written exam

Course Name: Artificial Intelligence and Machine Learning **Course Code:** 19

Prerequisite or Co-requisite: None

Number of Units: 2 Units

Unit Type: (1 Theoretical Unit - 1 Practical Unit)

General Objectives:

Familiarity with introductory concepts and basic topics of AI and problem-solving methods, and familiarity with modeling concepts, the position of machine learning in processing medical and biological data, familiarity with some important and practical machine learning algorithms.

Course Description:

Reviewing the use of artificial intelligence in prediction, diagnosis, and treatment of diseases.

Syllabus: (24 Theoretical Hours - 34 Practical Hours)

- Introduction to artificial intelligence and its place in the health system
- Familiarity with the basics of algorithm design
- Familiarity with data structure concepts
- Familiarity with the logic of thinking and rational thinking
- Familiarity with intelligent agents and the concept of rationality
- Familiarity with problem-solving and search
- Familiarity with the concept of informed and uninformed search
- Familiarity with Heuristic search
- Familiarity with game theory and optimal decision-making in games
- Introduction to artificial intelligence and its place in the health system
- Basics of modeling and model evaluation methods
- Familiarity with data types and their place in the analysis of models based on health data
- Basics of supervised or unsupervised methods
- Familiarity with the basics of feature extraction methods
- Basics of feature reduction methods such as PCA
- Familiarity with the basics of linear and non-linear regression methods
- Familiarity with the basics of neural networks
- Familiarity with some important classification methods

Main Course Resources:

1. J. Haugeland, Artificial Intelligence - MIT Press, Last Edition.
2. E. Alpaydin, Introduction to machine learning, MIT press, Last Edition.
3. S. Marsland, Machine learning, an algorithm perspective, CRC press, Last Edition.

Student Evaluation Method: In this course, the student will be evaluated through a written exam and practical projects.

Course Name: Internship in Knowledge-Based Companies, Research Centers related to Biomaterials, or Clinical Centers

Course Code: 20

Prerequisite or Co-requisite: None

Number of Units: 1 Unit

Unit Type: Internship

General Objectives:

To enhance the operational performance of residents as much as possible and to align theoretical findings from classes with the field conditions of biomaterial sciences in the design, production, and control stages, as well as meeting clinical needs related to pharmaceutical biomaterials. Residents can undertake practical internships in any of the aforementioned centers. This course helps residents to not only improve their own training for their research thesis topic but also to conceptualize, process it in that environment, and also prepare the ground for their future career path.

Course Description:

Acquiring practical skills by the student in a practical work environment (industry or clinical).

Course Description:

- Familiarity with methods of production and evaluation of pharmaceutical biomaterials
- Familiarity with the application of pharmaceutical biomaterials in disease treatment
- Training/Familiarity with the application of biomaterials in treatment with antimicrobial drugs
- Training/Familiarity with the application of biomaterials in targeted drug delivery
- Training/Familiarity with the application of biomaterials in cell modeling for conducting pharmacological studies based on identified clinical needs

Syllabus: (51 Internship Hours)

Internship in an environment based on topics coordinated by the department with knowledge-based companies or research centers or clinical settings.

- Familiarity with Translational Pharmaceutical Sciences applications
- Design and production of pharmaceutical biomaterials based on disease treatment
- Investigating the application of pharmaceutical biomaterials in drug delivery
- Transdermal drug delivery in patients requiring long-term drug therapy (Implants and patches)
- Targeted drug delivery in cancer
- Application of pharmaceutical biomaterials in designing drug models based on

inflammatory processes; design of biosensors for rapid analysis of prognostic biomarkers in patients

- Application of pharmaceutical biomaterials in designing biological indicators
- Design of biosensors for rapid analysis of diagnostic biomarkers in patients
- Application of pharmaceutical biomaterials in the design of novel vaccines
- Application of pharmaceutical biomaterials in designing hemostasis control systems (designing various types of hydrogels for controlling bleeding in patients undergoing surgery or with acute bleeding injuries)
- Application of pharmaceutical biomaterials in designing surfaces and devices with disinfectant/antimicrobial properties (Antimicrobial surfaces vs biofilms) and evaluation of mechanisms of microbial resistance development to the designed materials and devices
- Application of pharmaceutical biomaterials in infection and contamination control
- Design of cellular drug delivery models for conducting integrated drug studies
- Application of biomaterials in designing micro physiological systems for preparing cellular models for pharmacological studies
- Application of pharmaceutical biomaterials in coagulation management (ECLS using PCB coating + factor XII inhibitor)
- Application of pharmaceutical biomaterials in tissue engineering for designing disease models and their usage in studies related to disease treatment
- Use of biomaterial tools to investigate treatment progress in neonatal and pediatric intensive care units
- The role of biosensors in continuous monitoring of vital signs of hospitalized patients in intensive care units
- Application of biomaterials in designing skin biosensors for blood glucose monitoring in hospitalized patients
- Application of biomaterials in designing electrochemical biosensors for identifying cancer biomarkers
- Application of biomaterials in monitoring blood and cellular levels of drugs

Main Course Resources:

1. Biomaterials Science: An Introduction to Materials in Medicine 4th Edition
2. by William R Wagner (Editor), Shelly E. Sakiyama-Elbert (Editor), Guigen Zhang (Editor), Michael J. Yaszemski (Editor)-2020

Student Evaluation Method:

- Mid-term exam 25%
- Final written exam 50%
- Assignments 15%
- Attendance and active participation in class 10%

Course Name: Nano-toxicology **Course Code:** 21

Prerequisite or Co-requisite: None

Number of Units: 2 Units

Unit Type: Theoretical

General Objectives:

Study of toxic-kinetics, toxicity, and distribution of nanodrugs under in vivo conditions.

Course Description:

Study of the toxicity of drugs and drug delivery systems.

Syllabus (34 Theoretical Hours)**:**

- Introduction to nanotoxicology - Biodistribution of nanoparticles - Interaction of nanoparticles with biological membranes
- Interaction of nanomaterials with genes - cells
- Pulmonary and cardiovascular effects of nanoparticles

Main Course Resources:

1. Recently published research and review articles.
2. Nanotoxicology: Characterization, Dosing and Health Effects. Monteiro-Riviere NA, Informa Healthcare. The Latest edition.
3. Nanotoxicology: Interactions of Nanomaterials with Biological Systems. Zhao Y, Nalwa HS, American Scientific Publishers. The Latest edition.
4. Nanotoxicology (journal), Informa Healthcare.

Student Evaluation Method:

20% Class exam, and 80% Final exam (essay format), and 30% of the final exam questions are multiple-choice.

Course Name: Peptide and Protein Chemistry **Course Code:** 22

Prerequisite or Co-requisite: None

Number of Units: 2 Units

Unit Type: Theoretical

General Objectives:

The aim of presenting this course is familiarity with the concepts and advanced principles of protein chemistry, protein analysis, as well as methods for determining protein structure.

Course Description:

Study of the physical and chemical structure of peptides and proteins.

Syllabus (34 Theoretical Hours):

1. Introduction to the chemical structure of proteins
2. Theoretical basis in the separation of proteins from biological sources; Separation and purification of proteins: i. Liquid Chromatography 1 ii. Liquid Chromatography 2 iii. Separation and purification of proteins iv. Electrophoresis 1 v. Electrophoresis 2
3. Study of the primary structure of proteins
4. Determining the amino acid sequence from the amino terminus
5. Peptide mapping
6. Study of the primary structure of proteins
7. Mass spectrometry
8. Study of the primary structure of proteins a. Post-translational modifications
9. Proteomics and its application in pharmacology
10. Protein chemistry and its application in the quality control of biological products
11. Methods for analyzing the secondary, tertiary, and quaternary structure of proteins (Protein Folding, refolding)
12. Basics of protein-protein interaction
13. Basics of protein modeling and its application in pharmacology

Main Course Resources:

1. Protein Purification: Principles, High-Resolution Methods, and Applications. Janson JC. Rydén L. WILEY-VCH, The latest edition.
2. Proteins and Proteomics: A LABORATORY MANUAL, Simpson RJ, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, The latest edition.
3. Proteins Structure and function. John DW, 2005, John Wiley and sons.
4. Biological Mass Spectrometry, 2005, METHODS IN ENZYMOLOGY, VOL.402, Elsevier.
5. DISCOVERING GENOMICS, PROTEOMICS, AND BIOINFORMATICS, A. Malcolm Campbell and Laurie J. Heyer, 2003 Pearson Education, Inc., publishing as Benjamin Cummings,

Student Evaluation Method:

Written exam: 80 percent, and Seminar: 20 percent

Course Name: Medical Ethics in Pharmaceutical Biomaterials **Course Code:** 23

Prerequisite or Co-requisite: None

Number of Units: 1 Unit

Unit Type: Theoretical

General Objectives:

Familiarity with ethical considerations and the use of pharmaceutical biomaterials.

Course Description:

The utilization of pharmaceutical biomaterials requires them to be practical and economical, while the application of their products must also be ethical.

Syllabus (17 Theoretical Hours)

- Ethical considerations for clinical trials, animal experiments, industrial support, intellectual property regulations, and the patent system.
- Legal considerations (civil and criminal laws, design guarantees, insurance regulations, production, and sales).
- Social considerations of sales and marketing of products.
- Strategies of the global biomaterials system.
- Risk analysis and control in biomaterial design.
- Pre-market approval and production controls.
- Cost-effectiveness and economic justification.
- Technology management.

Main Course Resources:

Based on the opinion of the respective professor

Medical Ethics written by Dr. Bagher Larijani

Student Evaluation Method:

Formative: Seminar presentation, active participation in class, questions and answers

Summative: Written exam

Course Name: Novel Techniques in Smart Drug Delivery **Course Code:** 24

Prerequisite or Co-requisite: None

Number of Units: 3 Units (2Theoretical Unit - 1Practical Unit)

Unit Type: Theoretical - Practical

General Objectives:

Considering the need for controlled directional drug delivery, increasing the amount of transfer, and reducing drug wastage, action can be taken for targeted delivery of small amounts of drugs in a short time frame by relying on novel technologies.

Course Description:

Familiarizing the student with the physicochemical properties of the drug, its defined cellular target, various physical factors such as electric fields, magnetic fields, and ultrasound waves that can affect the direction, amount, depth, and speed of passage will be discussed. Given the increasing application of microchips and biosensors in the diagnosis and smart injection of drugs in pharmaceutical sciences and the growing interest of the pharmaceutical industry in producing smart electronic drugs, this course is taught.

Syllabus (34 Theoretical Hours - 34 Practical Hours)

- Diffusion laws in two-phase systems
- Dielectric coefficients, electric double layer, and types of potentials present at biological surfaces and quasi-colloidal systems
- Electric fields existing around macromolecules and biological membranes and the role of external electric fields
- The role of magnetic fields in creating electric fields and molecular traffic in biological tissue
- Mechanical resistance of biological membranes and the role of ultrasound waves in changing effective permeability in drug delivery; behavior of pharmaceutical biomaterials under specific electrical and magnetic conditions
- Investigating drug transfer through various barriers (transdermal, ocular) in a simulated virtual environment based on skin and cell membrane structure
- Electro permeabilization and its application in drug delivery
- Gene transfer and electroporation
- Electrotherapy for wound healing (Electrical Stimulation)
- Drug delivery using pore-forming chemical compounds and peptides (Pore forming peptides, and synthetic chemicals)
- Drug delivery using RF and microwave (MW) electromagnetic waves to specific tissue areas not feasible with conventional methods.
- Facilitating drug delivery using Infra Red waves; Hyperthermia
- Controlled release of drugs contained in hydrogels using electric fields (Electroresponsive
- Hydrogels in Drug Delivery)
- History of microchips and their evolutionary path and applications

- Internal structure of microchips
- Internal structure of biosensors, method of construction, application in smart drug injection
- Bio-batteries, method of construction and function
- History of RFID technology
- Internal structure of RFID microchips
- Technology of construction and application of RFID CHIP
- Performing practical tests with Smart Implant RFID
- Electrowetting and its application in pharmaceutical industries
- Internal structure of micropumps, method of construction and application
- Basic concepts in MEMS and NEMS
- Basic concepts in Open Loop and Close Loop control systems
- Method of construction and application of Drug Doses and Drug Reservoir
- Functioning of Self Regulating Responsive Therapeutic System

Main Course Resources:

1. Non-linear microscale alterations in membrane transport by electropermeabilization. Gowrishankar TR, Chen W., Lee RL. New York Annuals of Academy of Science. The latest edition.
2. Electricity and magnetism in Biology and Medicine. Bersani F, Springer, The latest edition.
3. Force Microscopy: Applications in Biology and Medicine. Jena BP, Hörber JKH, Wiley The latest edition.
4. Molecular Reaction Dynamics. Raphael D. Levine, Cambridge University Press, The latest edition.
5. Bioelectricity: A Quantitative Approach. Plonsey R, Barr RC, Springer, The latest edition.
6. Multi-scale Quantum Models for Biocatalysis: Modern Techniques and Applications (Challenges and Advances in Computational Chemistry and Physics). York DM, Lee TS, Springer, The latest edition.

Student Evaluation Method:

- Final written exam 70%
- Active participation in class and practical exam 30%

Chapter 4

Standards of the program

Standards of the educational Program

The Secretariat of the Supreme Council for Medical Sciences Planning of the Ministry of Health in the Islamic Republic of Iran has established the following standards for educational programs. These are the minimum topics that must be reviewed during the evaluation of educational programs by evaluators.

*It is essential, that the general educational spaces and facilities required, such as dedicated classrooms, conference halls, private book shelves in public libraries, computer centers equipped with sufficient internet speed, specialized software, a dedicated website for the department, and an educational filing system, be available.

*The essential, department must provide the required specialized spaces, including dedicated laboratories, hospital and social areas, as outlined in the educational program, for learners.

*The essential, department must also provide the necessary welfare and cultural spaces, such as faculty rooms, student rooms, service areas, prayer rooms, dormitories, and cultural and sports facilities.

*It is essential, that external educational areas, including those for rotational courses, be definitively approved by the group of evaluators.

*It is essential, that specialized populations and materials required for training, including active hospital beds, laboratory samples, food, medicinal, or cosmetic samples, be made available in sufficient numbers and acceptable diversity as per the educational program and evaluated by the evaluators.

*It is essential, the capital and consumable equipment needed for the program must be provided to the program's implementers, and their quality must also be approved by the evaluators.

* It is essential, adequate facilities for educational practice and related research in line with the specific field under evaluation must be accessible to faculty members and learners and approved by the evaluators.

*It is essential, department under evaluation must provide the required faculty members based on the items listed in the educational program and the decisions of the Expansion Council, and documentation of this should be made available to the evaluators.

*It is essential, that the educational department provides the required training courses for participants and staff according to the educational program plan, ensuring such programs are accessible to all intended audiences.

*It is essential, that regulations, guidelines, protocols, and educational policies be made available to all stakeholders. Participants must be informed and oriented regarding these at the beginning of the course. Documentation related to these regulations should also be made available to evaluators.

* It is essential, teaching resources, including books and journals required by both trainees and faculty members, must be accessible in the educational group's library.

* It is essential, participants must attend their workplace actively throughout the week, based on the number of days specified in current regulations, and carry out their duties under the supervision of instructors or senior trainees. The weekly or monthly schedule of the group must also be readily accessible.

* It is essential, the content of theoretical classes must align with at least 80% of the topics listed in the curriculum and course table outlined in the educational plan.

* It is essential, trainees must actively participate in all educational and research activities of the group—such as internal conferences, seminars, practical tasks, research projects, and teaching lower-level groups—according to the group's established schedule. Documentation of this participation must be provided to evaluators.

* It is essential, the skill-training process during the program must meet the relative satisfaction of trainees and receive evaluator approval.

* It is essential, dress code regulations must be clearly communicated to trainees, and appropriate, evaluator-approved mechanisms must be in place within the department for monitoring compliance.

* It is essential, trainees must be aware of the ethical codes included in the curriculum, adhere to them in practice, and their adherence must be verified by evaluators.

*It is essential, that the educational department provide the required training courses for trainees and staff, as specified in the educational program, ensuring these courses are properly organized and made accessible to all intended participants.

*It is necessary, that all educational regulations, instructions, guidelines, policies, and rules be made available to all stakeholders. Trainees must receive proper orientation regarding these at the beginning of the program, and relevant documentation must be provided to evaluators.

* It is essential, educational resources, including books and journals required by both trainees and faculty members, must be available in the educational group's library.

* It is essential, trainees must maintain active presence at their workplace throughout the week, in accordance with the number of days specified in the current regulations, and perform their duties under the supervision of instructors or senior trainees. The group's weekly or monthly schedule must also be accessible to all concerned parties.

* It is essential, the content of theoretical classes must align with at least 80% of the topics listed in the course table outlined in the official educational program.

*It is essential, that trainees actively participate in all educational and research activities of the group according to the group's scheduled program, including internal conferences, seminars, practical assignments, research projects, and teaching lower-level groups. Documentation of such participation must be made available to evaluators.

* It is essential, the skill-training process throughout the program must meet with the relative satisfaction of trainees and receive formal approval from evaluators.

* It is essential, dress code regulations must be clearly communicated to trainees, and appropriate, evaluator-approved monitoring mechanisms must be established within the department to ensure compliance.

* It is essential, trainees must be familiar with the ethical codes outlined in the curriculum, apply them in practice, and their adherence must be verified and approved by evaluators.

*It is essential, that an educational portfolio (Portfolio) be established for each trainee within the educational group. This portfolio must include evaluation results, certificates of educational activities (both internal and external to the educational group), commendations, warnings, and any other necessary documentation.

* It is essential, the dress code must be communicated to trainees at the beginning of the program, and appropriate and evaluator-approved implementation mechanisms must be in place within the department for its monitoring

*It is necessary, that trainees maintain an acceptable logbook/portfolio reflecting the general and specific competencies outlined in the educational program, which will be subject to evaluation.

* It is necessary, trainees must perform and document the required specialized interventional skills based on the items specified in the curriculum for each academic semester, and obtain the necessary supervising faculty's signature and approval.

* It is necessary, the logbook/portfolio must be continuously updated by trainees and monitored by the relevant instructors, who must provide written feedback on a regular basis.

*It is necessary, that trainees actively participate in the research activities of the academic group throughout the training period, and all related documentation must be made available for review.

* It is necessary, trainees must receive official certification from the responsible field supervisor, and such documentation must be submitted to the evaluation team for verification.

* It is necessary, there must be pre-planned and scheduled interdisciplinary collaborations between the main educational group and other educational groups. Supporting documentation demonstrating these collaborative efforts must be available for review.

* It is necessary, at a minimum, 70% of the teaching methods and techniques outlined in the curriculum must be utilized during the training process.

* It is necessary, throughout the program, trainees must undergo assessment through the evaluation methods specified in the curriculum, and the results of these evaluations must be submitted to the evaluation committee.

* It is necessary, the university or training centers under evaluation must meet all the criteria and standards outlined in the educational program.

Chapter Five

Evaluation of the Educational Program

Program Evaluation

Methods of Evaluating the Program:

Final evaluation conditions of the program:

This program will be evaluated under the following conditions:

- Three years have passed since the program was implemented
- Major technological changes that demonstrate the need for the program's technology
- Decisions of key policymakers related to the program

Program evaluation indicators:

Indicators	Criteria
• Graduates' satisfaction with the program	60%
• Level of satisfaction of faculty members with the program	70%
• Level of Satisfaction of Health System Managers with the Program Results	70%
• The extent to which health needs are estimated and problems are resolved by graduates of the field	According to the evaluators
• Quantity and quality of intellectual and research work by graduates of the field	According to the evaluators

Program Evaluation Methodology:

- Conducting surveys among involved faculty members, residents (trainees), and graduates using pre-reviewed questionnaires.
- Utilizing existing questionnaires provided by the evaluation and accreditation office.

Responsible Body for Program Evaluation:

The evaluation of the program is overseen by the Expansion Council of Medical Sciences Universities, in collaboration with the program drafting or revision committee, other educational offices, and relevant faculty members.

Procedure for Curriculum Revision:

The revision process for this program follows the steps outlined below:

- Gathering information from surveys, comparative and field research, suggestions and opinions from experts
- Request from the Secretariat to form an inspection committee.
- Presentation of Collected Data: Reviewing and discussing the collected data within the revision committee.

- Reviewing the required parts of the program and submitting a draft of the revised educational program to the Secretariat of the Supreme Council for Medical Sciences Planning.

Appendices

Appendix No. 1

Patients' Rights Charter in Iran

1) Receiving appropriate healthcare services is a fundamental right of every patient.
-Healthcare services must be provided:

1-1) With dignity and respect for human values, cultural beliefs, and religious principles.

1-2) Based on honesty, fairness, courtesy, and compassion.

1-3) Without any form of discrimination, including race, ethnicity, religion, type of illness, or gender.

1-4) In accordance with up-to-date medical knowledge and best practices.

1-5) Prioritizing the best interests of the patient.

1-6) Equitably distributed based on justice and treatment priorities in the allocation of health resources.

1-7) Coordinated across all aspects of care, including prevention, diagnosis, treatment, and rehabilitation.

1-8) Accompanied by access to all necessary and basic welfare facilities, avoiding unnecessary pain, suffering, and restrictions.

1-9) With special attention given to the rights of vulnerable groups in society such as children, women, pregnant women, the elderly, psychiatric patients, prisoners, individuals with physical or mental disabilities, and those without guardians.

1-10) Delivered in the shortest possible time while respecting the patient's time and schedule.

1-11) Tailored to the characteristics of service recipients, including language, age, and gender.

1-12) Provided free of charge in cases of emergency and urgent care, regardless of the patient's ability to pay. For non-emergency (elective) cases, delivered according to defined regulations and criteria.

1-13) In urgent and emergency situations, if proper care cannot be provided at the current facility, it is essential that necessary initial care and information be given, followed by timely transfer to an equipped center.

1-14) In the final stages of life, when the patient's condition is irreversible and death is imminent, the primary goal is to ensure their comfort. By "comfort," we mean the relief of pain and suffering, as well as attention to the patient's psychological, social, spiritual, and emotional needs — along with those of their family — during the dying process. A dying patient has the right to be accompanied by the person they wish to have with them during their final moments.

2) Information must be provided to the patient in an appropriate and sufficient manner.

2-1) The content of the information should include the following:

2-2-1) The provisions of the Patients' Rights Charter at the time of admission.

2-1-2) Predictable conditions and costs related to hospital services, including both medical and non-medical services, insurance regulations, and an introduction to available support systems upon admission.

1-3-2) The names, roles, and professional ranks of the responsible medical team members, including physicians, nurses, and students, as well as their professional relationships with one another.

1-4-2) Diagnostic and treatment methods, including the advantages, disadvantages, and potential complications of each method; diagnosis, prognosis, and its possible complications; and all other information that may influence the patient’s decision-making process.

1-5-2) How to access the treating physician and key members of the medical team throughout the course of treatment.

1-6-2) All procedures that have a research nature.

1-7-2) Necessary education to ensure continuity of care after discharge.

2-2) The manner of providing information should be as follows:

2-1-2) Information must be given at an appropriate time, taking into account the patient’s condition — such as anxiety, pain, and individual characteristics like language, level of education, and comprehension ability.

This requirement may be waived only if:

Delaying the start of treatment in order to provide this information would cause harm to the patient. In such cases, the information must be conveyed at the earliest appropriate opportunity after the necessary intervention.

The patient explicitly refuses to receive information, despite being informed of their right to do so. In this case, the patient's request must be respected, unless withholding information places the patient or others at serious risk.

2-2-2) The patient has the right to access all recorded information in their clinical file, obtain copies of it, and request corrections of any inaccuracies.

3) The patient's right to free choice and autonomous decision-making regarding the receipt of healthcare services must be respected.

3-1) Scope of Patient Choice and Decision-Making Includes the Following:

1-1-3) Choosing a treating physician and healthcare facility, within the framework of applicable regulations.

1-2-3) Requesting a second medical opinion or consultation from another physician.

3-1-3) Voluntary participation or refusal to participate in any form of research or clinical trial, with assurance that their decision will not affect the quality or continuation of care they receive.

1-4-3) Accepting or refusing proposed treatments after being fully informed of the potential risks and consequences associated with either acceptance or refusal — unless the refusal pertains to cases of self-harm or where the refusal may place another person at serious risk.

3-1-5) Expressing advance wishes regarding future medical interventions at a time when the patient still has decision-making capacity. These statements should be documented and used as guidance for healthcare providers and substitute decision-makers in the event the patient becomes incapacitated, while adhering to legal standards and ethical considerations.

3-2) Conditions for Patient Choice and Decision-Making

3-1-2) The patient’s choice and decision-making must be free, informed, and based on receiving the sufficient and comprehensive information outlined in section (2) above.

3-2-2) Sufficient time must be given to the patient after the provision of information to allow for thoughtful decision-making and selection.

4) Healthcare services must be delivered with respect for the patient’s privacy, confidentiality, and personal space.

4-1) Maintaining confidentiality regarding all patient-related information is mandatory, except in cases where the law provides specific exceptions.

4-2) Privacy must be respected at all stages of care, including diagnostic and therapeutic procedures. To ensure this, all necessary facilities and arrangements must be made.

4-3) Access to patient information must be limited to: The patient themselves, the treating medical team, individuals authorized by the patient, parties legally permitted access under existing laws.

4-4) The patient has the right to be accompanied by a trusted person during diagnostic examinations and procedures.

4-5) It is the right of every child to have one of their parents present throughout all stages of treatment, unless doing so contradicts medical necessity.

5) Access to an efficient system for handling complaints is a fundamental right of every patient.

5-1) Every patient has the right to file a complaint with the relevant authorities if they believe their rights as stated in this charter have been violated, without any disruption to the quality of care they receive.

5-2) Patients have the right to be informed about the process and outcome of their complaint.

5-3) Any harm resulting from errors committed by healthcare providers must be compensated in the shortest possible time following investigation and confirmation, in accordance with applicable regulations.

In the implementation of this charter, if the patient lacks the capacity to make decisions for any reason, all patient rights outlined in this charter will be exercised by the legal substitute decision-maker .However, if the substitute decision-maker makes a choice that contradicts the medical recommendation and hinders the patient’s treatment, the physician may request a review of the decision through the appropriate legal authorities .In cases where the patient lacks full decision-making capacity but is still able to make reasonable decisions regarding certain aspects of their treatment, their decisions must be respected .

Appendix No. 2

Executive Regulation on Dress Code and Professional Ethics for Students in Laboratory-Clinical Settings

The manner of dress and behavior of all personnel working in the field of medical sciences must be such that, while preserving professional dignity, it facilitates appropriate and effective professional communication with patients, patient companions, colleagues, and others in educational settings. Therefore, adherence to the following regulations is ethically mandatory for all individuals who are studying or providing services within clinical and laboratory educational environments.

Chapter One: Uniform and Dress Code

The clothing and attire of students entering educational environments—particularly clinical and laboratory settings—must be standardized and must meet the following specific characteristics:

1. White long coat, reaching down to the knee, non-form-fitting, with long sleeves.
2. The white coat must bear the official emblem of the University of Medical Sciences and the corresponding healthcare service provider.
3. All buttons of the coat must remain fully fastened at all times while present in educational settings.
4. It is mandatory to wear a valid, photo-bearing identification card containing the following information: First letter of the first name, Full surname, Faculty name, Field of study.
5. The ID card must be clearly displayed on the left chest area of the attire throughout the time spent in educational environments.
6. Female students must cover their entire head, neck, collarbone area, and hair with an appropriate covering (e.g., hijab).
7. Trousers must be full-length, standard, and non-form-fitting.The use of ripped jeans or similar casual pants is not acceptable in medical professional settings.
8. It is required to wear plain socks that fully cover the feet and lower legs (calves).
9. Wearing open-weave socks or socks with decorative elements is prohibited Shoes must be comfortable, appropriate for a professional setting, and noiseless during walking.
10. The coat, clothing, and shoes must be clean, neat, and of conventional appearance. Bright, flashy, or unconventional colors are not permitted.
11. The use or display of non-medical insignia or decorations attached to the coat, trousers, or shoes is strictly prohibited.
12. Wearing or displaying any type of rings, bracelets, necklaces, or earrings, except for a wedding ring, is prohibited in educational settings.

13. Wearing slippers or sandals is not allowed in educational environments, except in operating rooms and delivery rooms.

Executive Regulation on Dress Code and Professional Ethics for Students in Laboratory-Clinical Settings

Chapter Two: Personal Hygiene and Grooming Standards in Educational Settings

1- Personnel affiliated with the medical profession are role models for cleanliness and personal hygiene. Therefore, there is no doubt that appearance, cleanliness, and hygiene in medical educational environments are essential.

2- Nails should be short and clean. Nail decoration with nail polish and nail stickers in any form is prohibited. The use of artificial nails and long nails increases the chance of transmitting infection and the possibility of harming others and medical equipment.

3- Unconventional or excessive grooming of the face and hair that contradicts professional standards is not allowed.

4- Visible tattoos or body piercings (e.g., nose rings, facial jewelry) on hands, face, or other visible body parts are strictly prohibited.

5- The use of strong, intense, or allergenic perfumes and colognes in educational and clinical settings is prohibited.

Chapter Three: Student Conduct in Medical Educational Environments

1- Observing professional ethics, humility, and modesty when interacting with patients, patient companions, faculty members, fellow students, and staff is mandatory.

2- Conversations in educational settings should be conducted calmly and respectfully. Any kind of loud talking, noise-making, or uttering words unbecoming of the medical profession is strictly forbidden.

3- Smoking or using tobacco products is prohibited at all times while present in any educational setting.

4- Chewing gum or similar items is not permitted in laboratories, conference halls, patient rounds, or in the presence of faculty, staff, or patients.

5- During classes, lab sessions, and patient rounds, mobile phones must be turned off. At other times, their use should be limited to essential needs only.

6- Any kind of conversation or joking in common public areas such as elevators, cafeterias, and restaurants is prohibited.

Chapter Four: Supervision and Follow-Up of Regulation Violations

1- Supervision compliance with the principles of this regulation in teaching hospitals and other educational environments of clinical medical sciences is the responsibility of the hospital's educational deputy, the group manager, the head of the department, and the educational and student experts of the relevant unit.

2- In cases of persistent violations, they will be referred to the Student Disciplinary Council for further action.

Appendix No. 3

Regulations for Working with Animals Laboratory

Animals play a very important role in advancing and expanding medical science research. Ethical principles and teachings of divine religions dictate that we must respect their rights. Therefore, researchers conducting studies involving animals are obligated to adhere to the relevant ethical principles. For this reason, based on resolutions by the Publications Committee, mentioning the ethics committee code in research articles submitted to scientific journals is mandatory. There are the principles and regulations concerning work with laboratory animals:

1- The housing environment must be equipped with the necessary facilities to ensure the health of the animals.
2- Before introducing animals into the facility, all required conditions appropriate to their species and type must be prepared.
3- Cages, walls, floors, and other structural components must be washable and capable of being disinfected.
4- In enclosed spaces, the necessary conditions in terms of lighting, oxygen, humidity, and temperature must be provided.
5- If animals are housed outdoors, they must have access to shelter.
6- The space and cage should be appropriate for the animal species.
7- Cages should allow the animal to rest.
8- During transportation of the animal, conditions such as temperature, lighting, and breathable air must be maintained from the place of acquisition to the final destination.
9- The vehicle used for transporting animals must be suitable and authorized.
10- The health status of the animal must be checked by the receiving personnel.
11- Quarantine procedures must be followed for newly arrived animals.
12- Animals must not be placed in proximity to their natural predators.
13- Cages must be within the view of the caretaker at all times.
14- There must be no possibility of animals escaping from their cages.
15- Unnecessary noises that may distress the animals must be eliminated from the environment.
16- There should be no risk of injury or harm to the animals during handling or movement.
17- The bedding and resting area of the animal must be cleaned regularly.
18- The housing area must be continuously cleaned and disinfected.
19- Standard disinfectants must be used for cleaning the environment and sanitizing equipment.
20- The food and water provided to the animals must be suitable and hygienic.
21- Ventilation and waste removal must be carried out continuously in a manner that prevents unpleasant odors, allergic reactions, and transmission of diseases to both staff members and laboratory animals.
22- An appropriate area must be designated for the disposal of animal carcasses.
23- Sufficient, comfortable, and hygienic facilities must be available for administrative staff, technicians, and caretakers.
24- Animals that are sick or in special physiological conditions (e.g., pregnant or lactating) must not be used in research.

25- Adequate time must be allowed for animals to acclimate to the environment and personnel before any research procedure begins.
26- Staff members must have received training in animal handling.

Conditions for conducting animal research

- ✓ The specific animal species selected for experimentation and research must be appropriate for the study.
- ✓ Only the minimum number of animals necessary to ensure statistical validity and scientific accuracy should be used.
- ✓ There must be no suitable alternative methods available that could replace the use of animals.
- ✓ At all stages of the research, and particularly in the method of euthanasia following the study, the least amount of distress should be inflicted on the animals.
- ✓ Codes of practice for working with animals must be followed throughout the entire duration of the study.
- ✓ The results should ultimately contribute to the improvement of public health.