

Biological Products Quality Control

کنترل کیفی فراورده های بیولوژیک

Course Type: Theory and Practice PhD students

Department: Biotechnology

Semester: 2nd semester 94-95

Number of Credits: 2

Time: 10-12 a.m. Wednesday

Place: In Coordination with the Lecturer

Course Coordinator: Dr. Ali Jahanian

	LECTURE	LECTURE R
1	Good manufacturing practice (GMP)- main concepts	Dr. Rezazadeh
2	Personnel, materials and equipment	Dr. Rezazadeh
3	Documentation and recording	Dr. Rezazadeh
4	Production, in-process and storage controls	Dr. Rezazadeh
5	Laboratory control and validation	Dr. Rezazadeh
6	Sterile manufacturing	Dr. Rezazadeh
7	Clean rooms and HVAC systems	Dr. Rezazadeh
8	sterilization processes for biological products	Dr. Rezazadeh
9	Stability study and shelf-life	Dr. Rezazadeh
10	Stability and instability of proteins	Dr. Rezazadeh
11	Endotoxins 1	Dr. Jahanian
12	Endotoxins 2	Dr. Jahanian
13	Amino Acid Analysis	Dr. Jahanian
14	Quality Controls of some Biopharmaceuticals (I)	Dr. Jahanian
15	Quality Controls of some Biopharmaceuticals (II)	Dr. Jahanian
16	Determination of Biological activity	Dr. Jahanian

Course Overview

Evaluation:

The final grade in this course will be based on the following:

Assignments	20%
Participation	10%
Final Project	20%
Tests and Exams	50%

References:

1. Biopharmaceuticals: biochemistry and Biotechnology. Gary walsh. John wiley & Sons Ltd, (1998).
2. Guide to Microbiological Control in Pharmaceuticals C. Denger. R. Barid, 2008
3. Pharmaceutical Microbiology W.B Hugo .A.D. Russell, 2009