

<b>Course Name</b>	<b>Code</b>	<b>Semester</b>	<b>Theoretical (hours/week)</b>	<b>Practice (hours/week)</b>	<b>Laboratory (hours/week)</b>	<b>ECTS</b>
<b>STEPS IN DRUG DEVELOPMENT PROCESS</b>	<b>BBM 533</b>	1 <sup>th</sup> /2 <sup>nd</sup> Semester	3	0	0	5
<b>Prerequisites</b>	None					
<b>Course Language</b>	Turkish					
<b>Course Type</b>	Elective					
<b>Teaching Methods</b>	Lecture, Discussion, Question-Answer					
<b>Instructor(s)</b>						
<b>Course Objective</b>	1- Learning the ways of finding new drugs 2- Pre-clinical evaluation in drug development 3- 3- To give information about how to do clinical studies					
<b>Course Learning Outcomes</b>	1- List the stages of drug development and define preclinical studies 2- Describes what in-vitro studies are and lists what and how to do phase studies. 3- Lists how to proceed with the licensing of drugs and describes what ethics committee permission should be.					
<b>Resources</b>	Klinik Farmakolojinin Esasları ve Temel Düzenlemeler. Prof. Dr. S. Oğuz KAYAALP . 5 baskı.2013					

## WEEKLY COURSE TOPICS

Weeks	DISCUSSION TOPICS TO BE PROCESSED
1.	New ways of finding drugs
2.	Pre-clinical studies
3.	Clinical trial periods in drug development: Phase 1
4.	Clinical trial periods in drug development: Phase 2
5.	Clinical trial periods in drug development: Phase 3
6.	Clinical trial periods in drug development: Phase 1
7.	Ethical aspects of clinical drug research
8.	Midterm exam
9.	Clinical drug research in special age groups (drug research in children)
10.	Clinical drug research in special age groups (drug research in the elderly)
11.	Clinical drug research in special age groups (drug research in pregnant women)
12.	Patent and data protection in medicine
13.	Article Discussion
14.	Article Discussion
15.	Final Exam

### ECTS/ WORKLOAD TABLE

Activities	Number	Duration	Total Work load
Course	14	3	42
Laboratory			
Practice			
Field Study			
Outclass course work hours ( Self working / Teamwork / Preliminary work)	16	3	48
Presentations (Video preparation / Poster preparation / Oral presentation / Focus group discussion / Applying questionnaire/ Observation and report writing)			
Seminars	1	8	8
Project			
Case Study			
Role playing, dramatization			
Preparing and criticizing article			
Semester midterm exams	2	10	20
Semester final exams	1	7	7
<b>The total Workload (hours)/25 (S)</b>	125/25 = 5		
<b>ECTS</b>	<b>5</b>		

## EVALUATION SYSTEM

Semester Work	The number of	Contribution
Midterm Exam	1	25%
Quiz		
Laboratory		
Practice		
Field Study		
Specific practical training (If exists)		
Homework Assignments		
Presentations and Seminars	1	25%
Projects		
Other evaluation methods		
<b>Total of Midterm Studies</b>		50%
<b>Final Studies</b>		
Final	1	50%
Homework assignment		
Practice		
Laboratory		
<b>Total of Final Studies</b>		50%
Contribution of midterm studies to course grade		50%
Contribution of final studies to course grade		50%
<b>Total Grade</b>		100

## COURSE LEARNING OUTCOMES THE PROGRAM WITH THE ASSOCIATION QUALIFICATIONS

Program Qualifications		Course Learning Outcomes		
		LO1	LO2	LO3
1.	Degree level qualification in the field of Biological and Biomedical Sciences based on the expertise level up-to-date information, enhances and deepens.	4	4	4
2.	Biological and Biomedical Sciences field requires a level of information technology, technical equipment and machinery and tools that are specific to the field information	4	4	4
3.	In the field of biological and Biomedical Sciences extrapolates integrate with information from different disciplines to create new information, comments, analysis and synthesis by using different research methods and propose solutions.	4	4	4
4.	The report of his research the author.	4	4	4
5.	Empirical research plans.	4	4	4
6.	Biological and Biomedical Sciences brings solutions within the field, solves the problems, assesses the results obtained when necessary.	4	4	4
7.	Biological and Biomedical Sciences Field and public health-related priority issues scientific clinical and/or descriptive research/presentations/publication.	4	4	4
8.	Biological and Biomedical Sciences related field evaluates information critically.	4	4	4
9.	Biological and Biomedical Sciences in the field of professional development and lifelong learning policy applies in the work performed.	4	4	4
10.	Biological and Biomedical Sciences, and current developments in the field of information, and their work in the same field or with groups other than the written, oral and Visual systematically as he discusses and shares.	4	4	4
11.	The professional environment, social relationships, and those relationships are a critical perspective, norms and makes the need to improve them.	4	4	4
12.	Biological and Biomedical Sciences in the field of data collection, interpretation, announcing towards restriction, social, scientific and ethical values in oversees and teaches these values.	4	4	4
13.	Biological and Biomedical Sciences is the basic unit of society, current developments in the field of children's and family to include national values and evaluates in line with the realities of	4	4	4

	the country.			
<b>14.</b>	Ethical principles and rules are important to the individual and society, ethics.	<b>4</b>	<b>4</b>	<b>4</b>
<b>15.</b>	Biological and Biomedical Sciences in the field with strategy, policy and implementation plans and results obtained within the framework of the quality processes.	<b>4</b>	<b>4</b>	<b>4</b>

**Qualification Level:** 1 Provide: Low, 2: low/medium, 3: medium, 4: High, 5: Excellent