SYLLABUS

Date/ Revision : 30 January 2017/0
Faculty : Life Sciences
Approval : Dean, The Faculty of Life Sciences

SUBJECT : PHARMACEUTICAL ENGINEERING PROCESS DESIGN

1. Identification of Subject:

Name of Subject : **Pharmaceutical Engineering Process Design**
Code of Subject : PEPD-3800
SKS : 2
Semester : 5
Study Program : Chemical Engineering
Lecturer : Tutun Nugraha, Ph.D

2. Competency

The course provides an introduction to the essential operations used in the manufacture of pharmaceutical products. The course discusses the pharmaceutical product life-cycle, variability, testing, and specifications of pharmaceutical ingredients. This course prepares the students before they are focusing themselves on the manufacturing steps used in production of the Pharmaceutical Product or Dosage Form.

3. Description of Subject:

Various topics related to the process of development, production and quality control in Pharmaceutical Industries are discussed. The concept of API (Active Pharmaceutical Ingredients), and formlations are given. Furthermore, the concepts or drug action, Routes of drug administration Mechanism of oral medication, Drug absorption, bioavailability, and activity, Pharmacokinetic profile of oral and I.V. dosage forms, Metabolism, or biotransformation of drugs, Bioavailability, bioequivalence, and generic drugs, Safety and the toxic effects of drugs will also be discussed. Some aspects of regulatory are also given including the concept of GMP (Good Manufacturing Practices). Moreover, some environmental aspects are also given.

4. Learning Approach

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Approach : Expository, inquiry, collaborative
Method : Lecture presentation, Focus group discussion, team work
Student Task : Appraisal, group presentation about biomaterial innovation
Media : Power Point presentation, print out of journals

5. Evaluation

a) Absence maximum : 25%
b) Discussion and semester appraisal : 40 points
c) Final Examination (Project + Final test) : 60 points

Total : 100 points

6. Contents/ Topics of Lecturing:

Week	Topics	Content	Remark
1	Introduction to Pharmaceutical Process and Industry	• General Overview of the course • Development of the pharmaceutical industry and its impact • Important milestones in the introduction of pharmaceuticals • The multidisciplinary nature of pharmaceutical sciences • Medicinal trees • Pharmaceutical research and development • Pharmaceutical technology • Pharmaceutical economics • The world pharmaceutical market • ethics in the pharmaceutical industry	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 1 1 x 2 x 50 minutes
2	Drugs, medicines, and regulatory authorities	• Drugs and medicines: brand names and generic names • Drug names • Drug discovery and the drug development process • Marketing of generic drugs in the USA or Europe • The role of pharmacopoeias • Regulatory agencies	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 3 1 x 2 x 50 minutes
3	Bulk drugs or active pharmaceutical ingredients	• Bulk drugs and bulk drug plants Lab to manufacturing level scale-up Bulk drug manufacturing • Solubility of API • Stereoisomeric bulk drugs • Stability, degradation, and impurity profiles of bulk drugs • Drug development, scale up • analytical development	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapetr 4 1 x 2 x 50 minutes

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		• Green chemistry in bulk drug manufacturing	
4	Formulated drugs 1	• The role of excipients • The classification of dosage forms • Formulation and manufacturing of tablets • Problems with tablet manufacturing and the use of process analytical technology Liquid dosage forms • Production of oral solution and suspension dosage forms • Dosage forms in pediatrics	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 5 1 x 2 x 50 minutes
5	Formulated drugs 2	• Dosage forms according to route of administration • The parenteral route of administration The pulmonary route of administration	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 6 1 x 2 x 50 minutes
6	The stability of medicines	• Stability – an essential criterion of medicines • Label instructions and stability of medicines at home • Drug stability kinetics • Stabilization of pharmaceutical products The International Conference on Harmonization	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 7 1 x 2 x 50 minutes
7, 9	Quality assurance in medicines	• The concept of quality assurance Evolution of quality testing and safety of medicine • Quality management systems • Good manufacturing practice in sterile production (GMP) • Validation • Contamination control in formulation factory • Limits of good quality	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 8 2 x 2 x 50 minutes
8	Mideterm Break		
10, 11, 12	Pharmacological concepts and drugs	• Drug action • Routes of drug administration Mechanism of oral medication • Drug absorption, bioavailability, and activity • Pharmacokinetic profile of oral and IV dosage forms • Metabolism, or biotransformation of drugs	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 9 3 x 2 x 50 minutes

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		• Bioavailability, bioequivalence, and generic drugs • Safety and the toxic effects of drugs • The ideal pharmacokinetics and pharmacodynamics of a drug	
13	The top five most common or long-selling drugs	• Amoxicillin – the largest-selling b-lactam antibiotic • Aspirin – the longest-selling drug on the market • Paracetemol – the best-selling antipyretic analgesic • in the world • Ranitidine – the world's leading prescribed drug • Ciprofloxacin – the best-selling antibacterial in the world	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 10 1 x 2 x 50 minutes
14	New pharmaceutical technology and pharmaceuticals	• Biologics • Nanomedicines by nanotechnology • Regenerative medicines • Transdermal patch technology	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 13 1 x 2 x 50 minutes
15	Counterfeit drugs and drug abuse	• Counterfeit drugs • Anticounterfeiting strategies • Risks of internet pharmacies • Drug abuse	"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford Chapter 12 1 x 2 x 50 minutes
16, 17	Final Exam		

7. Book Reference:

"An Introduction to Pharmaceutical Science", Jiben Roy, Biohealthcare Publishing Oxford, 2011

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