Basic Pharmaceutical Technology

**Practical Information**

**Status:** Compulsory

**Time schedule:** 5th semester

**Teaching methods:** Lectures, classroom lessons, practicals, work group. Student will be encouraged to participate with their work in different problems solving, case studies and short seminars and projects.

**Dimension of course:** 6 ECTS-points.

**Number of hours:** 25 lectures of 45 min, 5 classroom lessons (practical application of theory and problem solving ability) of 45 minutes, 15 classes x 45 min work group, 25 practicals (experimental work and report writing) of 45 minutes, and 10 classes x 45 min. project and report writing.

**Frequency:** Once a year.

**Evaluation:**
- Continuing: 50 points
- Final: 50 points

A student can pass the subject without a final exam if he/she collects at least 71 points throughout the semester with the following mark scale:
- 71-76 points – 6
- 77-82 points – 7
- 83-88 points – 8
- 89-94 points – 9
- 95-100 points – 10

**Teaching material:**
- Simov, *Pharmaceutical Technology*; 2001
- Eur. PH.,
- USP,
- BP,
- BNF,
- USP DI

**Purpose:**
The objective of the course is to get the students familiar with basic pharmaceutical operations commonly used during magistral compounding and industrial production. It is a priority to learn the art, science, and the correct procedures in order to extemporaneously compound a prescription product and then put this knowledge into practice in the laboratory class. Major incompatibilities give to the student an insight into the complexity of the dosage forms, dosage form production, packaging and dosage form stability. The basics of the pharmaceutical production are then compiled (with basics of formulation and production of a
stable product (stability testing and importance of the stability testing during formulation, preformulation and production, in order to understand the principles and factors controlling drug stability). The basics of good manufacturing practice and validation as legal and practical aspects of drug production and drug quality are also emphasised.

Pre – requests:
General background knowledge required to complete this subject area can be found in the content of the courses: biophysics, physical pharmacy, social pharmacy, microbiology, and evaluation of pharmacopoeial substances

Content:
Official compendia, Pharmaceutical technology and pharmacy practice, Prescription and regulations, Good pharmacy practice, compounding and dispensing techniques; Basic pharmaceutical incompatibilities, (drug-drug, drug-excipient, drug-container, Excipient-container); Pharmaceutical technology and industry (large scale production), Good manufacturing practice, basics of and standards for, Validation, basics of, Pharmaceutical technology and small scale production; Basic pharmaceutical operations, Mechanical operations, Heat operations, Diffusion operations, Sterilization; Drug stability and stability testing

Outcome:
The aim of the course is the student:
• to get familiar with basic pharmaceutical operations commonly used during magistral compounding and industrial production
• to explore different drug-drug, drug-excipients, drug-container, excipient-container interactions,
• to understand the stability of the dosage form, to discuss stability studies during formulation and preformulation, and stability as a quality control parameter
• to discuss the various factors influencing the drug quality.
• to discuss the demands for and the contents of a quality assurance program.
• to explain the GMP demands for drug production.

Student load:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lectures</td>
<td>25</td>
</tr>
<tr>
<td>Preparation for lectures</td>
<td>25</td>
</tr>
<tr>
<td>Classroom lessons</td>
<td>5</td>
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<tr>
<td>Preparation</td>
<td>5</td>
</tr>
<tr>
<td>Practicals</td>
<td>25</td>
</tr>
<tr>
<td>Preparation for practicals</td>
<td>10</td>
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<tr>
<td>Work group</td>
<td>15</td>
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<tr>
<td>Project</td>
<td>10</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>120</strong></td>
</tr>
<tr>
<td>Evaluation</td>
<td>60</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>180</strong>hours</td>
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</tbody>
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Course responsible:
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