



## INSTITUTE OF NEUROSCIENCE AND PHYSIOLOGY

### **FAB810 Preclinical Drug Development: Drug Metabolism and in Vitro/in Vivo Predictions, 7.5 credits**

Preklinisk läkemedelsutveckling: läkemedelsmetabolism och in vitro/in vivo prediktioner, 7,5 högskolepoäng

*Second Cycle*

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#### **Confirmation**

This course syllabus was confirmed by Committee for Study Programmes in Pharmacy on 2010-01-11 and was last revised on 2020-11-13 by Institute of Neuroscience and Physiology to be valid from 2020-11-13, spring semester of 2021.

*Field of education:* Pharmacy 100%

*Department:* Institute of Neuroscience and Physiology

#### **Position in the educational system**

The section for pharmacology. The course is given as an elective course on semester 8, second cycle in the pharmacy programme, Göteborgs universitet.

The course can be part of the following programme: 1) Programme in Pharmacy (F2APO)

#### **Entry requirements**

For admission to the course it is required that all courses up to semester seven in the pharmacy programme has been gone through.

#### **Learning outcomes**

On completion of the course, the student is expected to independently be able to:

##### *Knowledge and understanding*

- Apply advanced pharmacokinetic knowledge when results from different species, including scaling to man, are compared and evaluated.
- Present pros and cons of different methods used under pre-clinical drug development for study of absorption, distribution and metabolism of substances.

- Demonstrate familiarity with bioanalytical methodology for quantification of drugs and their metabolites in biological liquids.

#### Skills and ability

- Present a good ability to independently analyse experimental data by means of spreadsheet programs and modelling by means of non-linear regression.
- Complete a scientific report on performed experiments.
- Acquire generic knowledge of methodology and procedures at non-linear regression.

#### *Judgement and approach*

- Present a good ability to analyse and evaluate complex pre-clinical knowledge of importance for selection of substance for continued drug development.

### **Course content**

The course provides advanced knowledge of how absorption, distribution and metabolism of drugs is studied in non-clinical studies and how achieved results can be used to predict the pharmacokinetics of the substance in man. The course is based on and deepens earlier courses in pharmacology, medicinal chemistry, statistics and pharmacokinetics.

Knowledge of how substances are absorbed, distributed, metabolised and excreted is of great importance for selection of appropriate candidate substances in the development of future drugs. The course addresses how drugs and other exogenous substances are turned over in the organism and how these processes are regulated. The course provides understanding of how such knowledge contributes to rational drug development. During the course, different experimental systems are introduced and evaluated (sub-/cellular systems, organ preparations, in vivo) to characterise the biotransformation and turn over of substances. Emphasis is on issues of importance to pre-clinical drug development. During the course, methods are introduced for identification of metabolic enzymes and evaluation of the potential of drug-drug interaction (induction, inhibition) with relevant modelling (enzyme kinetics). Methods for bioanalysis of drugs in biological liquids, as well as methodology for structure determination of metabolites are introduced. The course gives insight in how results of non-clinical studies can be used to predict the pharmacokinetic properties in man.

The course includes 7.5 credits, of which laboratory sessions with report constitute 5 credits and presentation of advanced assignment 2.5 credits.

### **Form of teaching**

*Language of instruction:* English and Swedish

The teaching material is mainly in English. Teaching, as well as the examination, may completely or partly be in English.

### **Assessment**

Written report of laboratory sessions and written and oral presentation of advanced assignment. Compulsory part with requirements of attendance is start of the course, laboratory sessions and seminars in connection with advanced assignment. The number of examination sessions is limited to five. Possibility to supplement failed compulsory parts can be given, at the earliest, at the next course date and only in case of a vacancy.

The student has the right to change examiner after having failed twice on the same examination, if it is practically possible. The application shall be sent to the board of the department and has to be in writing. In case the course has ceased or gone through larger changes the student should be guaranteed access to at least three examination sessions (including the regular examination session) during a time of at least a year with starting point of the earlier planning of the course.

### **Grades**

The grading scale comprises: Pass (G) and Fail (U).

### **Course evaluation**

Course evaluation meeting with students and course administration are held when the course is completed. Course is completed with an electronic course evaluation which after compilation is presented to the students.

### **Additional information**

The teaching is given as lectures, laboratory sessions, group work and seminars. The course is partly based on independent problem-solving as a form for learning.