

6.00 credits

54.0 h

Q1 and Q2



This learning unit is not open to incoming exchange students!

Teacher(s)	. SOMEBODY ;Elens Laure ;
Language :	French
Place of the course	Bruxelles Woluwe
Learning outcomes	At the end of this learning unit, the student is able to : Propose and justify choices when selecting : analytical methods for quality control (identification and dosage) of drugs and active substances, a PAT technique for monitoring the same active ingredient during its manufacturing process, a method for dosing the active ingredient in a biological matrix in order to study its fate in the body, 1 validation criteria to demonstrate the reliability of the results provided by the above-mentioned methods. The use of statistical tools in laboratory data processing, with a focus on the pharmaceutical industry. The aim is to provide guidelines in the various areas of the pharmaceutical industry. The course should be oriented towards practical applications, combining microcomputing and statistical tools to make them easy to use.
Evaluation methods	The examination for the module could be placed outside the official June session. Written examination for the statistics part (with computer) and oral for the rest in front of the other teachers. In the event of exceptional circumstances, examination arrangements may be modified.
Teaching methods	Classroom lectures and practice sessions. Materials are available free of charge on Moodle (not compulsory) or distributed to students.
Content	Part of the course covers the qualitative analysis of drugs, the quantitative analysis of active substances and in-process controls. The definition of the "PAT" concept is then addressed, as well as the analytical aspect through vibrational spectroscopy (near infrared, mid infrared and Raman) and data processing (chemometrics) with the help of examples from the scientific literature. Introduction to fundamental notions and concepts for the validation of quantitative analytical methods. The course is structured around the following points: 1. Purpose of validation 2. Validation criteria 3. Validation protocols 4. Application examples Introduction: philosophy of the statistical approach. Basic statistics applied to quality control: normality of distribution, sampling, statistical risks, regression and correlation. Statistical process control (SPC): control charts, continuous and discontinuous process control, sampling frequency and methods. Statistics and quality: sample selection and size, comparison tests, linear and non-linear regression. Multidimensional analysis methods.
Faculty or entity in charge	FARM

Programmes containing this learning unit (UE)				
Program title	Acronym	Credits	Prerequisite	Learning outcomes
Advanced Master in Industrial Pharmacy	FARI2MC	6		