LEARNING MODULE DESCRIPTION

GENERAL INFORMATION

1. Module title: **Pharmaceutical Analysis**
2. Module code:
3. Programme title: **Chemistry**
4. Cycle of studies:
5. Year of studies (where relevant): **second year**
6. Terms in which taught (summer/winter term):
7. Type of classes and the number of contact hours: **Lecture: 15 hrs, laboratory: 30 hrs**
8. Number of ECTS credits: **5**
9. Name, surname, academic degree/title of the module lecturer/other teaching staff/ e-mail: Module lecturer: **prof. Marta Krysmann, MKrysmann@uclan.ac.uk**

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10. Language:**English**

DETAILED INFORMATION

1. Module aim (aims)

The aim in this module is to present the principles of analytical techniques used to assure the quality of medicines.

In essence, the multidisciplinary nature of this module will enhance students understanding of modern techniques employed in drug discovery. This includes a variety of techniques ranging from the principles and applications of titrimetric analysis and spectroscopic techniques in the analysis of pharmaceuticals, such as, UV and IR spectroscopy. The principles of chromatographic separation: basic gas and liquid chromatography, size exclusion, ion exchange, chiral separations, and method development. An introduction to mass spectrometry and the interfaced tandem techniques, GC/MS and LC/MS. Methods of inorganic analysis, including, for example, atomic absorption and atomic emission spectroscopy.

The module will use a system of lectures and workshops to deliver the material; these will be supported by a series of laboratory classes that will further develop the practical skills in organic and analytical chemistry. The lecture programme is organised to enable the student to link different concepts and develop the material. It will not be used to just provide the basic information. Consequently, it is important that thestudents read the suggested directed reading material in addition to attending the lecture. The workshops will be used to provide further development of the lecture material in order to enable a greater appreciation of the concepts of pharmaceutical analysis. These workshops will follow the general format of theory and then practice through exercises. The students will be expected to perform six practical experiments. For each practical the students will be expected to answer questions based on the workand produce a report. Finally, in order to complete and pass the module, the

students will take a final exam where the theoretical and practical knowledge will be assessed.

2. Pre-requisites in terms of knowledge, skills and social competences (where relevant)

During the course of studies, the student will build an understanding of modern analytical methods used in determination of product purity.In order to develop the skills, the student should have knowledge and understanding in chemistry and chemical calculations. The student is also required to possess basic laboratory skills and be able to follow health and safety regulations in the laboratory.

READING LIST

1. Modern Analytical Chemistry – David Harvey – published in 2000 by The McGraw-Hill Companies
2. Introduction to Pharmaceutical Chemical Analysis – Steen Honore Hansen et al – published in 2012 by Wiley
3. Pharmaceutical Chemical Analysis: Methods for Identification and Limit Tests – Ole Pedersen – published in 2006 by CRC Press Taylor & Francis

SYLLABUS:

15hours of lectures and workshops:

Lecture 1 – 1h
Safe & Effective Medicines
Drug and drug standards
Regulations and agencies
Certification
The pharmacist as a QP
Tests and specifications
Analytical procedures and validation
Lecture 2 – 1h
Physical & Chemical Properties
Bulk physical properties
Physicochemical properties
Lecture 3 – 1h
Titrimetric Analysis
Workshop – 2h
Titrimetric analysis / calculations
basic calculations, redox, Fe, sulfanilamide
Lecture 4 – 1h
UV-Visible Spectroscopy
Overview
Absorption
Beer-Lambert Law

Instrumentation
Workshop – 2h
UV
Tablet Assay
% of stated content
% w/w of active ingredient in the formulation
Lecture 5 – 1h
IR Spectroscopy
Overview
Practical examples
Lecture 6 – 1h
Chromatography
Lecture 7 – 1h
HPLC and GC
Workshop – 2h
Chromatography
TLC - the limit tests for known/unknown impurities
Calculating the percentage of stated content in a drug using the calibration curve in HPLC
Calculating the concentration of active ingredient and the deviation from the specific content based on the single point calibration against an internal standard in HPLC
Lecture 8 – 1h
Atomic Spectroscopy
Overview
Atomic Absorption Spectroscopy
Atomic Emission Spectroscopy
Lecture 9 – 1h
Mass Spectrometry
Overview
Ionisation Methods
Analyzers

30 hours of laboratories:
Fe tablets - titration
Synthesis of aspirin
Synthesis of sulphanilamide
Separation by means of ion exchange chromatography
Separation by means of molecular exclusion Chromatography (size exclusion chromatography)
Citalopram and its Forced Degradation Products under Alkaline Conditions
To discuss the lab equipment and chemicals available– uv, ir, hplc, chromcolumns , etc.

STUDENT WORKLOAD (ECTS credits)

Module title:	
Activity types	Mean number of hours* spent on each activity type
Contact hours with the teacher as specified in the programme	45
Preparation for laboratory project	20
Study of the results from laboratory	15
Reading of the indicated literature	10
Writing of the reports	15
Preparation for exam	20
Total hours	125
Total ECTS credits for the module	5

** Class hours – 1 hour means 45 minutes*

#Independent study – examples of activity types: (1) preparation for classes, (2) data analysis, (3) library-based work, (4)writing a class report, (5) exam preparation, etc.

GRADING SYSTEM:

5	EXCELLENT – outstanding performance	(91-100%)
4+	VERY GOOD – above the average standard with only minor errors	(81-90%)
4	GOOD – generally sound work with some minor errors	(71-80%)
3+	SATISFACTORY – fair but with a number of notable errors	(61-70%)
3	SUFFICIENT – fair but with significant shortcomings	(51-60%)
2	FAIL	below 51%