**ANALYTICAL METHODS DEVELOPMENT AND VALIDATION**

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| Module designation | *Analytical Methods Development and Validation* |
| Semester(s) in which the module is taught | *1* |
| Person responsible for the module | 1. Prof. Dr. rer.nat. apt. M. Yuwono, MS **(Course Coordinator)**<br>2. Dr. apt. Asri Darmawati, MS |
| Language | *Bahasa Indonesia* |
| Relation to curriculum | *~~Compulsory / elective /~~ specialisation* |
| Teaching methods | *lecture, discussion, assignment* |
| Workload (incl. contact hours, self-study hours) | *(Estimated) Total workload:*<br>*Contact hours (structured activities.): 90,67 hours*<br>*Private study including independent learning activites*: *90,67 hours* |
| Credit points | *2 SCU / 6 ECTS* |
| Required and recommended prerequisites for joining the module | *NA* |
| Module objectives/intended learning outcomes | Students are:<br>LO1: Able to realize excellence based on religious morals (excellence with morality), able to work together, and show a responsible attitude to work in their field of expertise independently<br>LO2: Able to internalize the spirit of independence, struggle, and entrepreneurship<br>LO4: Able to develop a pharmaceutical professional performance with analytical acumen in solving pharmaceutical problems and managing research in the pharmaceutical field related to national and global systems and policies, both inter and inter-disciplinary approaches.<br>LO5: Able to access and review information through an Information and Communication Technology (ICT) system, decide on a specific subject of study, maintain the feasibility of implementing research designs, conduct research, analyze data, conclude research results comprehensively, and create strategic issues based on the study that reflect the latest updates in the field of pharmaceutical sciences, and communicate them in the media and scientific forums at the national and international level through an interdisciplinary or multidisciplinary approach in the form of a thesis or other equivalent forms.<br>LO12: Able to develop analytical methods to ensure the quality of drugs, cosmetics, foods, and beverages.<br>LO15: Able to plan and organize concepts and procedures for quality assurance and recommendations on pharmaceutical products, which include drugs, cosmetics, foods, and beverages as products and therapeutic goods. |

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| Content | The Advanced Chromatography course describes the development of chromatographic instrumentation and sample preparation, the application of chromatographic methods for the analysis and development of pharmaceutical materials and preparations, including those concerning preparative chromatography. |
| Exams and assessment formats | *Take-home written assignments* |
| Study and examination requirements | *The final grade in the module is composed of 25% presentation 65% take-home assignments, 10% in-class participation and soft-skills assessment. Students must have a final grade of 70% or higher to pass* |
| Reading list | 1. *J. Emmer and J. H. M. Miller (Eds), 2005, Method Validation in Pharmaceutical Analysis. A Guide to Best Practice, Weinheim: WILEY VCH Verlag GmbH & Co. KGAA.*<br>2. *S. Ahuja and M.W. Dong, 2005. Handbook of Pharmaceutical Analysis by HPLC, Elsevier, Amsterdam.*<br>3. *N. Grinberg and Rodriguez, 2019, Ewing's Analytical Instrumentation Handbook, Fourth Edition, CRC Press, Taylor & Francis Group, New York*<br>4. *USP 43, Chapter 1225, Validation of Analytical Procedures*<br>5. *USP 43, Chapter 1226 , Verification of Analytical Procedures*<br>6. *USP 43, Chapter 1224, Transfer of Analytical Procedures*<br>7. *USP 43 Chapter 621, Chromatography.* |