BIOPHARMACEUTICAL PRODUCTS

Module designation	*Biopharmaceutical Products*
Semester(s) in which the module is taught	*2*
Person responsible for the module	1. apt. Mahardian Rahmadi,S.Si.,MSc.,Ph.D **(Course Coordinator)** 2. Prof. apt. Junaidi Khotib, S.Si., M.Kes.,Ph.D. 3. Prof. Dra. apt. Esti Hendradi, M.Si., Ph.D.
Language	*Bahasa Indonesia*
Relation to curriculum	*~~Compulsory~~ / elective / ~~specialisation~~*
Teaching methods	*lecture, discussion, assignment*
Workload (incl. contact hours, self-study hours)	*(Estimated) Total workload:* *Contact hours (structured activities.): 90,67 hours* *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: 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 LO2: Able to internalize the spirit of independence, struggle, and entrepreneurship 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 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. LO6: Able to make decisions in the context of solving problems related to science and technology development based on analytical or experimental studies through collaboration with colleagues, colleagues in institutions and research communities at both national and international levels and utilizing research results for the benefit of the user and other communities LO9: Able to carry out molecular manipulation of substances and develop formulations and manufacturing of pharmaceutical preparations with active pharmaceutical ingredients derived from natural products and synthetic compounds through the manufacture of polymorphs, nanoparticles, solid dispersions LO11: Able to develop systems for evaluating the bioavailability of drugs in the body, pharmaceutical products circulation permits, and their in-vitro and in-vivo evaluations with specific delivery systems with appropriate analytical methods. LO14: Able to build drug management systems from active pharmaceutical ingredients to finished products that are ready for therapeutic uses. 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.

Content	Biopharmaceutical Products presents various aspects required for the production of biopharmaceutical preparations including the underlying external mechanisms such as post-translational modifications and their effects on preparation quality.), cells (stem cells) including formulations, production processes and quality control of preparations needed. Testing the final product for safety and effectiveness in the required preclinical and clinical trials.
Exams and assessment formats	*Final exam (100 minutes), presentation (100 minutes), take-home written assignments*
Study and examination requirements	*the final grade in the module is composed of 40% performance on final exams, 25% quizzes, 25% 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. Modern Biopharmaceutical, Knablein Jorg, Wiley-Vch, Germany, 2005 2. Post Translational Modification of Protein Biopharmaceutical, Walsh G., Wiley-Blackwell, 2009 3. Biotechnology and Biopharmacutical, Transforming protein and genes into drugs, Rodney J.Y & Gibaldi M., Wiley-Liss, 2003 4. Preclinical safety evaluation of Biopharmaceuticals, a science-based approach to facilitating clinical trials, Cavagnaro J.A, Wiley, 2007 5. Biopharmaceutical production technology, Subramanian G, Wiley-VCH, 2012 6. Biopharmaceutical drug design and development, Wu-Pong S. & Rojanasakul Y., Humana Press, 2008