SOLID PREPARATION FORMULATION PLAN

Module designation	*Solid Preparation Formulation Plan*
Semester(s) in which the module is taught	*2*
Person responsible for the module	1. Prof. Dr. apt. Dwi Setyawan, S.Si., M.Si. **(Course Coordinator)** 2. Dr. apt. M.L Ardhani D.L,S.Si.,M.Pharm.Sci
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 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 LO12: Able to develop analytical methods to ensure the quality of drugs, cosmetics, foods, and beverages. 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	This lecture describes the development of solid dosage forms, the manufacturing stages of pharmaceutical dosge forms including particle size reduction, granulation, drying, compression processes and their effect on the quality of pharmaceutical products, the concept of Quality by Design (QbD), Process Analytical Technology (PAT), Design of Experiment (DoE) and Statistical Process Control (SPC) as supporting and analytical tools of the production process for achieving the good quality of pharmaceutical products.
Exams and assessment formats	*Final exam (100 minutes), take-home written assignments*

Study and examination requirements	*the final grade in the module is composed of 100% performance on final exams and take-home assignments. Students must have a final grade of 70% or higher to pass*
Reading list	1. Augsburger, Larry L., and Stephen W. Hoag, eds. *pharmaceutical dosage forms-tablets*. CRC Press, 2016. 2. Aulton, Michael E., and Kevin MG Taylor, eds. *Aulton's Pharmaceutics E-Book: The Design and Manufacture of Medicines*. Elsevier Health Sciences, 2017. 3. Lawrence, X. Yu, et al. "Understanding pharmaceutical quality by design." *The AAPS journal* 16.4 (2014): 771- 783. 4. Allen, Loyd, and Howard C. Ansel. *Ansel's pharmaceutical dosage forms and drug delivery systems*. Lippincott Williams & Wilkins, 2013. 5. Hickey, Anthony J., and David Ganderton. *Pharmaceutical process engineering*. CRC Press, 2016. 6. Indonesia, Kementrian Kesehatan Republik. "Farmakope Indonesia edisi ke-5 Buku II." *Jakarta: Kementrian Kesehatan Republik Indonesia* 1240 .2015. 7. Swarbrick, James. *Encyclopedia of pharmaceutical technology*. CRC Press, 2013. 8. Lawrence, X. Yu. "Pharmaceutical quality by design: product and process development, understanding, and control." *Pharmaceutical research* 25.4 (2008): 781-791. 9. Wu, Huiquan, Maury White, and Mansoor A. Khan. "Quality-by-Design (QbD): An integrated process analytical technology (PAT) approach for a dynamic pharmaceutical co-precipitation process characterization and process design space development." *International journal of pharmaceutics* 405.1-2 (2011): 63-78. 10. Matthews, Paul G. Design of Experiments with MINITAB. ASQ Quality Press. 2005. 11. Eriksson, L., Johansson, E., et al. Design of Experiments: Principles and Applications. Third revised and enlarged edition. Umetrics Academy. 2008