DRUG SURVEILLANCE

Module designation	*Drug Surveillance*
Semester(s) in which the module is taught	*2*
Person responsible for the module	Prof. Junaidi Khotib, S.Si.,Apt.,M.Kes.,Ph.D **(Course Coordinator)**
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. LO3: Able to develop and build logical-critical-systematic-creative thinking and scientific conceptions through scientific research, design creation, or artworks of science and technology that pays attention to and applies humanities values through an interdisciplinary or multidisciplinary approach in the form of a thesis or other equivalent forms. 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.

	LO7: Able to analyze natural materials to obtain active ingredients and/or pharmaceutical excipients with due observance of nature conservation. LO8: Able to carry out drug designs through the synthesis of bioactive compounds based on the structure-activity relationship. 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. LO13: Able to design drug development both from natural products and/or synthetic compounds by considering the biological mimicry system. LO14: Able to build drug management systems from active pharmaceutical ingredients to finished products that are ready for therapeutic uses.
Content	The Drug Surveillance course presents the concept of drug safety and regulations, pharmacovigilance concepts related to drug use, identification of ADR and AE, monitoring of drug use in patients, conducting DUR-DUS, quantitatively and qualitatively reviewing safety data, actual ADR and AE and potential to occur in the use and prevention efforts.
Exams and assessment formats	*Mid term exam and final exam*
Study and examination requirements	*the final grade in the module is composed of 45% mid term exam, 45% final exam , 10% in-class participation and soft-skills assessment. Students must have a final grade of 70% or higher to pass*
Reading list	1. *Bhattacharya, M, Scarazzini L, Pharmacovigilance: A Practical Approach, 1st edition, Elsivier, 2019* 2. *Cobert B, Gregory WM, Thomas JL, Cobert's Manual of Drug Safety and Pharmacovigilance: 3rd Edition , World scientific publisher, 2019*