	MODULE DESCRIPTION **S1 PHARMACEUTICAL DEPARTMENT OF CHEMISTRY, FMIPA UNIB** **PHARMACEUTICAL TECHNOLOGY ON STERILE DOSAGE FORM (STERILE PREPARATION TECHNOLOGY)**					**S1F-41**
	Module Code : FRS-553	Credit Points (T/P): (2 / 1)	Semester: 3 (Three)	MK Clump : Pharmacy and Pharmaceutical technology	Study Program Coordinates : Dwi Dominica, S.Farm. Apt. M.Farm	Authorization :
	Revision to : 00	Edition Revision :-		Responsible Person : Delia Komala Sari, S.Farm., Apt., M.Farm (DKS)		

Intended Learning Outcomes (ILO/CP)	**ILO/CP-PRODI :** 1. (STN8)- Show attitude responsible on jobs in the field of his skills by independent ; 2. (KU1) Capable apply thinking logical , critical , systematic , and innovative in context development or implementation knowledge knowledge and caring technology _ and apply score appropriate humanities _ with field his expertise ; 3. (KU2) Able show performance independent , quality , and measurable ; 4. (KU11) Capable manage Duty independent and or Duty group ; 5. (KU12) Able take decision based on information and / or data ; 6. (KK4) Able To do mixing preparation sterile ; 7. (KK9) Able designing formulation preparation medicine ; 8. (KK10) Able To do analysis of parameters of physics , chemistry , physico-chemistry , and biological , material drug and or product medicine ; 9. (KK13) Able apply knowledge and technology in research pharmaceutical ; 10. (P4) Able consider requirements making preparation medicine ; 11. (P5) Able evaluate quality preparation medicine ; 12. (P6) Able ensure drug Fulfill requirements quality ;

	CP-MK : 1. Students are expected to be able to understand the route of administration, mechanism, system and parenteral drug administration; 2. Students are expected to be able to explain the meaning of sterile dosage, the principle of sterility and sterilization, the principle of guaranteeing sterility; 3. Students are expected to understand about water treatment for parenteral/sterile dosage; 4. Students are expected to be able to explain the meaning, test methods and methods of pyrogen removal; 5. Students are expected to understand the principle and calculation of tonicity; 6. Students are expected to be able to understand the characteristics and packaging requirements of parenteral dosage; 7. Students are expected to be able to understand about Large Volume Parenteral dosage; 8. Students are expected to be able to understand small volume parenteral dosage; 9. Students are expected to be able to understand about Filtration Theory; 10. Students are expected to be able to understand the stability of parenteral dosage (injections and infusions); 11. Students are expected to be able to understand about the Quality Control of Parenteral Dosage. 12. Students are expected to be able to understand about ophthalmic dosage and nasal dosage 13. Students are expected to be able to understand the Principles of Aseptic Room Control
Short Description	This course of Pharmaceutical Technology for Sterile Dosage learns about cGMP principles regarding the manufacture of sterile dosage, formulations of sterile dosage, methods and processes for the production of sterile dosage, principles of parenteral formulations, tonicity and methods of sterilizing equipment, materials, and pharmaceutical dosage.
Module Content	1. Parenteral Dosage; 2. Definition of sterile dosage, principles of sterility and sterilization, principles of guaranteeing sterility; 3. water treatment for parenteral/sterile dosage; 4. Definition, test methods and methods of pyrogen removal; 5. Tonicity; 6. Characteristics and packaging requirements of parenteral dosage; 7. Large Volume Parenteral Dosage; 8. Small Volume Parenteral Dosage; 9. Filtration Theory; 10. Stability of parenteral dosage (injection and infusion); 11. Quality Control of Parenteral Dosage.

	12. Ophthalmic dosage and nasal dosage 13. Aseptic Room Control Principle
Recommended Literatures	**Main :** 1. cGMP 2012 2. Sterile Pharmaceutical Technology **Supporters :** 1. Parenteral Technology Manual, pages 3 – 16 2. Pharmaceutical Dosage Forms: Parenteral Medication, volume 1, pp . 17 - 57 3. Pharmaceutical Dosage Forms: Parenteral Medications, pages 173 – 248 4. Pharmaceutical Technology Manual, pages 17 – 48 5. Troy, David, 2005, Remington: The Science and Practice of Pharmacy 6. Parenteral Technology Manual, pages 37 – 48 7. Martin's Physical Pharmacy and Pharmaceutical Sciences, 5th ed., pages 220-228 8. Pharmaceutical Dosage Forms: Parenteral Medication, volume 1, pages 249 – 282; volume 2, pages 93 – 101; 9. Parenteral Technology Manual, pages 63 – 72
Planned use/applicability	**Preset software :** OS:Windows ; office, **Device hardware :** PC & LCD Projector; Control system model automatic ;
Team Teaching	Delia Komala Sari, S.Farm., Apt., M.Farm Dwi Dominica S.Farm., Apt., M.Farm
Admission Requirements	Solid dosage pharmaceutical technology

Week	Sub-ILO/CP-Module	Indicator(s)	Assessment Types	Teaching Method(s) and Work Load [&Time	Module Content [&Literature]	Assessment Percentage (%)

				Estimate]		
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**
1	1. study contract , 2. Introduction to parenteral dosage	• Accuracy explain parenteral route of drug administration • Accuracy in explaining the principle of parenteral drug administration • Accuracy in explaining the system and problems of parenteral drug administration	• Online exercise/ quiz . • Textbook review • Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1x(1 x50")]** • Read text and ppt , observe pictures , **[TM: 1 x (1 x50")]**	Definition base parenteral dosage • Administration route • giving principle , • System and problems of parenteral dosage in the body **[** Parenteral Technology Manual, pages 173 – 248 **]**	5 %

2, 3	1. Definition of Sterile Dosage, 2. Principles of sterility and sterilization, 3. sterility assurance principle	• Accuracy of students in explaining what is meant by sterile dosage • Accuracy of students in explaining the principle of sterility and sterilization methods • Student accuracy explains the principle that guarantees sterility	•Online exercise/ quiz . •Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 2 x(1 x50")]** • Read text and ppt , observe image , **[TM: 2 x (1 x50")]**	• Wet heat sterilization method • Dry heat sterilization method • How to treat sterile products **[** Sterile Pharmaceutical Preparation Technology **]**	10%
4	water treatment for parenteral/steril e dosage	• Students' ability to understand and explain water management for sterile dosage	•Online exercise/ quiz . •Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]**	• privilege water solvent as solvent for various ingredient • method repair quality of water obtained from water sources , including : distillation , reverse osmosis, ionic exchange • method make and keep Water for Injection(WFI), USP. types of water, including potable water, water for	5 %

					injection, sterile waters for inhalation, injection and irrigation, bacteriostatic WFI, high purity water. • various water quality tests for dosage parenteral • materials used in water installations for parenteral dosage • how to provide clean steam (clean *steam*) on a sterile production unit	
5	Capable understand understanding , way test and method removal of p y rogen	• Students' ability to understand the meaning of pyrogen and endotoxin • Ability to understand the pyrogen test method • Ability to understand pyrogen removal methods	•Online exercise/ quiz . •Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]**	• Definition of p y rogen and endotoxin • Py rogen test method (rabbit test, LAL test, qualitative / quantitative) • Method disappearance p y rogen	5%

6	Able to understand, master and understand the principles and calculations of tonicity in the manufacture of pharmaceutical dosage	• Accuracy explains the meaning of tonicity • Accuracy in explaining the application of tonicity determination in the manufacture of parenteral dosage • Accuracy in calculating tonicity in pharmaceutical dosage • Accuracy in explaining the purpose of determining the tonicity of parenteral dosage	•Online exercise/ quiz . •Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observe image , **[TM: 1 x (1 x50")]** • (Task-1: Explain the purpose of determining isotonicity in pharmaceutical dosage (danchat forum), **[BT+BM:(1+1)x(4x60")]** • (Task-2: Calculate the tonicity value)	1. Definition of tonicity 2. Calculation of tonicity of parenteral dosage 3. Determination of isotonic, hypotonic and hypertonic in parenteral dosage	5%

7	Able to understand the characteristics and requirements of various types of packaging (containers and lids) for parenteral dosage	• Accuracy in understanding the packaging requirements of parenteral dosage • Accuracy describes the appropriate packaging classification	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]**	• Different types of primary packaging (containers and lids) • Characteristics, advantages and disadvantages of glass containers • Types of glasses for parenteral dosage and their characteristics • Tests on glass, including: powdered glass and water attack test • How to wash, sterilize and depyrogenate glass • Plastic Category • Characteristics, advantages and disadvantages of plastic containers • Additives in plastic container materials • Mention and explain the types of plastics • Characteristics of rubber cap • Types of rubber • Additives in rubber	5%
8	**Mid-Semester Evaluation (Online Exam)**					10%

9	Able to understand the definition and principles of large volume parenteral formulations (Large Volume Parenterals)	• Ability to understand the definition of large volume parenteral dosage • Ability to understand the principles of large volume parenteral formulations	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures , discussions group , **[TM: 1 x(2 x50")]**	1. Definition of LVP 2. Indications for use of LVP 3. The concept of LVP formulation, which includes: physiological parameters, physicochemical parameters and LVP . stabilization 4. Types of LVP which include: electrolyte solutions, carbohydrates and TPN 5. Processing conditions affecting LVP . formulations 6. Considerations in the LVP admixture 7. Additives required in the formulation of LV 8. Effect of viscosity, density, surface tension and vapor pressure in the LVP production system	5 %

10	Able to understand the definition and principles of small volume parenteral formulations (Small Volume Parenterals, SVP)	• Accuracy explains the definition of SVP • Accuracy in explaining the principle of small volume parenteral formulations • Ability to understand the selection of suitable carrier materials for parenteral dosage	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]**	• Definition of SVP • SVP categorizatio n by USP based on form his physique • Influence route giving (iv, im , sc etc.) against formulation preparation injection • Influence route gift to SVP formulation • Ingredient carrier (vehicle): water and non-water • Necessary considerations _ for choose ingredient carrier (vehicle) • Ways _ for increase solubility drug in water (cosolvent , surfactant , cyclodextrin) • Unit and method measure solubility drug • Influence structure molecule , style pull intermolecular , pH, and temperature to solubility medicine t	5 %

11	Able to understand filtration theory	• Ability to understand filtration theory • Accuracy in explaining filtration theory	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]**	• The types of filters include : screen filters, cake filters, depth filters and membrane filters.	5%
12	1. Stability of parenteral dosage (injection and infusion); 2. Quality Control of Parenteral Dosage.	• Accuracy explains the purpose of stability test • Accuracy describes the stability tests that need to be carried out on parenteral dosage	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]**	Definition of stability, stability test for parenteral dosage, quality control on parenteral dosage	5%

13, 14	Able to understand the theory and principles of formulation of ophthalmic dosage and nasal dosage	• Accuracy explains the principle of ophthalmic dosage • Accuracy explains the principle of nasal dosage • Accuracy of explaining ophthalmic product requirements • Accuracy in explaining the process of making ophthalmic dosage • Accuracy in explaining the process of making nasal dosage	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 2 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 2 x (1 x50")]**	1. Requirements product ophthalmic and nasal 2. Consideration in the process of manufacture preparation ophthalmic and nasal 3. Component nontherapeutic in solution and ophthalmic suspension 4. Component nontherapeutic in ointment *Ophthalmic*	10%
15	Able to understand the principles of aseptic room control in sterile production. (Sterile Preparation of cGMP)	• Ability to explain the principles of aseptic room control in the production process	• Online exercise/ quiz . • Textbook review Presentations (videos)	• Lectures & Brainstorming, Group Discussions , **[TM: 1 x(1 x50")]** • Read text and ppt , observepictures , **[TM: 1 x (1 x50")]** • (Task-1: Explain the purpose of aseptic room control (forums and chat), **[BT+BM:(1+1)x(4x60")]** • (Task-2: Finding AHU/HVAC air conditioning	• Technical definition • Draft and method ventilation air that produces air clean • Design and clean construction room • Personnel as source contamination • Risk analysis for determine monitoring program environment • Classification air room • How to monitor contamination microbiology in the air room How to monitor	5%

				system)	contamination microbiology on surface (*surfaces*)	
16	**Evaluation End of Semester (Online Exam)**					20%

Week	**Expected final learning outcomes**	**Material/Subject**	**Learning Strategies**	**Implementation Plan**	**Assessment Percentage (%)**
1	**2**	**3**	**4**	**5**	**6**
1	Able to know practical material, rules, inventory of tools, how to wash glassware, safety in the laboratory, and chemical material	Practical Assistant	Lectures and discussions	Groups 1 and 2	3%
2	Able to apply aseptic technique	Tool Sterilization	Pretest, practicum, discussion, report generation	Group 1	2%
3	Able to apply aseptic technique	Tool Sterilization	Pretest, practicum, discussion, report generation	Group 2	2%
4	Able to formulate and evaluate LVP dosage	Making 5% Dextrose Infusion	Pretest, practicum, discussion, report generation	Group 1	2%
5	Able to formulate and evaluate LVP dosage	Making 5% Dextrose Infusion	Pretest, practicum, discussion, report	Group 2	2%

			generation		
6	Able to formulate and evaluate normal saline infusion dosage	Making Infusion Normal Copy	Pretest, practicum, discussion, report generation	Group 1	2%
7	Able to formulate and evaluate normal saline infusion dosage	Making Infusion Normal Copy	Pretest, practicum, discussion, report generation	Group 2	2%
8					
9	Able to formulate and evaluate SVP dosage	Phenytoin Injection Manufacturing	Pretest, practicum, discussion, report generation	Group 1	2%
10	Able to formulate and evaluate SVP dosage	Phenytoin Injection Manufacturing	Pretest, practicum, discussion, report generation	Group 2	2%
11	Able to formulate and evaluate ophthalmic dosage	Making chloramphenicol eye ointment	Pretest, practicum, discussion, report generation	Group 1	2%
12	Able to formulate and evaluate ophthalmic dosage	Making chloramphenicol eye ointment	Pretest, practicum, discussion, report generation	Group 2	2%
13	Able to apply sterility test	Sterilization Test	Pretest, practicum, discussion, report generation	Group 1	2%
14	Able to apply sterility test	Sterilization Test	Pretest, practicum, discussion, report generation	Group 2	2%
15	Able to understand all practical material	Final review and response	Question and answer (practicum) dry)	Groups 1 and 2	20%
16	**PRACTICUM RESPONSE**				