MINISTRY OF HEALTH OF UKRAINE

Danylo Halytsky Lviv National Medical University

Department: ***Drug Technology and Biopharmaceutics***

Head of the Department: ***associate professor S.B. Bilous***

PRODUCTION PRACTICAL TRAINING REPORT

on " Industrial Technology of Drugs "

Full name of student _____

_____

Faculty: ***pharmaceutical*** Course year **4** Group _____

Lviv-201__

Student

_____

(full name)

undergoes production practical training on industrial technology of drugs

Period of practical training: from _____._____ to___.____ 201_

Supervisor of practical training from the Department

_____

(post, full name)

Sign of supervisor _____

GENERAL STATEMENTS

Period of practical training – 1 week. According to the academic curriculum, students undergo the production practical training on industrial technology of drugs in the 4th course year after studying the academic discipline "Industrial technology of drugs".

At the beginning of the practical training students must be given the instruction, syllabus and report on the practical training.

Student writes the report on the practical training according to the schedule of training and instructions of the supervisors from university.

Production practical training is assessed by 4-point grading scale and the mark is taken into the account for giving the stipend to a student along with other academic disciplines.

Student that have not met the requirements of practical training and got the negative reference about the work or negative mark for the report may be expelled from the university.

Purpose of the practical training on industrial technology of drugs is to achieve basic objectives determined by professional education program on speciality 7.12020101 "Pharmacy" and serves for forming the content of the practical training.

Final objectives of the production practical training on industrial technology of drugs:

- to deepen the knowledge gained in practical classes on industrial technology of drugs, develop and improve practical skills and abilities needed to solve the job problems under manufacturing conditions;
- to create the motivation in the future specialists systematically to refresh the knowledge base, to get acquainted with the latest achievements in the pharmaceutical industry, to review scientific literature, and to apply their knowledge and skills into the practice.

Objectives of practical training:

- familiarization with production organization at the pharmaceutical enterprises;
- generalization of knowledge gained from studying the normative documents, general pharmacopoeia articles, and use them in drug manufacturing;
- familiarization with technological equipment of pharmaceutical enterprises, scientific management of labor and prospects of the pharmaceutical manufacturing.

As a result of practical training, student should **be able to:**

- use normative documents and informative literature;
- make the working prescriptions;
- choose an optimal technology for manufacture of drug products with regard to the properties of active pharmaceutical ingredients and excipients;
- write material balance equations and calculate output, losses, factor of account at separate manufacturing stages;
- work with equipment for dosing the ingredients with different physical and chemical properties;
- calculate total volume of solution and concentration of solid components;
- calculate mass of active ingredients and excipients, medicinal plant raw material;
- make calculations for diluting and strengthening the solutions;
- create process flow diagrams for manufacturing different drug products, including intermediate quality control and standardization of finished product;
- control the quality of finished drug products, select packages for preparations.

During the practical training on industrial technology of drugs students write the reports.

Student is required to note in the practical training report:

- organization of the manufacture at the pharmaceutical enterprise;
- receiving of purified water, quality control and storage conditions;

- working prescriptions and manufacturing process of different drug products with consideration of factor of account: tablets, liquid preparations, semi-solid preparations, solutions for injection, tinctures, extracts (in accordance with task granted by supervisor from the Department);

- process flow diagrams for the manufacturing of drug products.

CONTENT OF THE PRODUCTION PRACTICAL TRAINING ON INDUSTRIAL TECHNOLOGY OF DRUGS

Practical training on industrial technology of drugs is performed at the Drugs Technology and Biopharmaceutics Department.

The goals of production practical training on industrial technology of drugs are to deepen the knowledge of students on the manufacture of drug products under industrial conditions; to know the basic stages of the manufacture of drug products under industrial conditions; to create manufacturing and apparatus schemes; to know the basic criteria and methods for quality control of intermediate and finished products.

PLAN OF THE PRACTICAL TRAINING

№	Topic	Hours	Date	Mark	Sign of supervisor
1	Safety training. General familiarization with manufacture organization at the pharmaceutical enterprises. **Manufacture of solid preparations** (production methods, equipment, quality control). Packaging of tablets; tablet packaging machines	6			
2	**Manufacture of liquid preparations** (production methods, equipment, quality control). Manufacturing stages of liquid preparations; nomenclature of aqueous and alcoholic solutions, syrups, aromatic waters, suspensions and emulsions that are produced under industrial conditions	6			
3	**Manufacture of semi-solid preparations and suppositories** (production methods, equipment, quality control). Stages of the manufacturing process, equipment for manufacture of homogeneous and heterogeneous semi-solid preparations.	6			

	Manufacture of suppositories under industrial conditions.				
4	**Manufacture of parenteral preparations** (manufacturing features, requirements of Pharmacopoeia). Construction and operation mechanism of ampoule making machines; pretreatment of ampoules for filling; preparing and filtration of solutions; ampoules filling; sterilization	6			
5	**Manufacture of extraction preparations** (production methods, equipment, quality control). Stages of the manufacturing process, equipment. Rectification and recuperation of ethanol.	4			
	Final control	2			

List of practical skills and abilities that student should get during the production practical training on industrial technology of drugs

1. To use normative documents, informative and scientific literature to solve practical tasks.
2. To write material balance equations and calculate output, losses, factor of account at different manufacturing stages of the drug products in different dosage forms.
3. To make working prescriptions with consideration of the factor of account for manufacture of solid preparations.
4. To make working prescriptions with consideration of the factor of account for manufacture of liquid preparations
5. To make working prescriptions with consideration of the factor of account for manufacture of semi-solid preparations
6. To make working prescriptions with consideration of the factor of account for manufacture of suppositories.
7. To substantiate the technology of solid, liquid, semi-solid preparations and suppositories in accordance to the composition.
8. To choose the equipment for manufacture of solid preparations.
9. To choose the equipment for manufacture of liquid preparations.

10. To choose the equipment for manufacture of semi-solid preparations

11. To choose the equipment for manufacture of suppositories.

12. To create the process flow diagrams for manufacturing drug products in different dosage forms.

13. To control quality of solid, liquid, semi-solid preparations and suppositories in accordance to the normative standards.

14. To select appropriate equipment for determination of the quality parameters of finished preparations in accordance to the Pharmacopoeia requirements

15. To make calculations for strengthening and diluting of solutions.

16. To normalize the concentration of solutions.

17. To use current requirements of GMP in the manufacture of sterile and aseptically produced drug products.

18. To make working prescriptions for manufacture of solutions for injection in ampoules.

19. To substantiate the choice of containers for solutions for injection with regard to physical and chemical properties of drug substances.

20. To control quality of sterile drug products in accordance with current normative standards.

21. To substantiate theoretically the choice of the extraction method of medicinal plant material.

22. To calculate mass of medicinal plant raw material and volume of extraction solvent for manufacture of extraction preparations.

23. To convert mass percent into the volume and vice versa for determining the concentration of water-alcohol solutions, to determine the concentration of water-alcohol solutions using alcoholometers and densimeters.

24. To control quality of extraction preparations in accordance with current normative standards.

Assessment criteria of practical skills of students:

- **5 points** – student correctly, clearly, logically and completely performs the task; makes integration of theory and practice; can generalize information and demonstrate

good practical skills; is able to substantiate the composition and technology of drug products, to select an appropriate package and to control the quality of finished products.

- **4 points** – student performs the task correctly; demonstrates good practical skills but makes slight mistakes; uses theoretical knowledge correctly to solve the practical tasks; can solve easy and average situational problems; has necessary practical abilities which exceed the basic minimum.
- **3 points** – student makes significant mistakes during the demonstration of practical skills, performs the practical task incompletely, solving only the easiest problems; has the necessary minimum of technological knowledge.
- **0 points** – student has performed less than 50% of the tasks from the thematic plan of the practical training and cannot give the logical answers, does not understand the material; makes significant mistakes during the demonstration of practical skills.

ASSESSMENT OF STUDENT'S WORK

DURING THE PRACTICAL TRAINING

№	Practical skills and abilities	Date	Mark	Sign
1.	To use normative documents, informative and scientific literature to solve practical tasks			
2.	To write material balance equations, to calculate output, losses and factor of account at different manufacturing stages of drug products in different dosage forms			
3.	To make working prescriptions for manufacturing of solid preparations with consideration of the factor of account			
4.	To make working prescriptions for manufacture of liquid preparations with consideration of factor of account			
5.	To make working prescriptions for manufacturing of semi-solid preparations with consideration of the factor of account			
6.	To make working prescriptions for manufacturing of suppositories with consideration of the factor of account			
7.	To substantiate an optimal technology for solid, liquid, semi-solid preparations and suppositories in accordance with composition of the preparations			

8.	To select equipment for manufacturing of solid preparations			
9.	To select equipment for manufacturing of liquid preparations			
10.	To select equipment for manufacturing of semi-solid preparations			
11.	To select equipment for manufacturing of suppositories			
12.	To create the process flow diagrams for manufacturing of drug products in different dosage forms			
13.	To control quality of solid, liquid, semi-solid preparations and suppositories in accordance with normative standards			
14.	To select equipment for determination of different quality parameters of finished products in accordance with pharmacopoeial requirements			
15.	To make calculations for strengthening and dilution of solutions			
16.	To normalize concentration of solutions			
17.	To be able to use current GMP requirements for production of sterile and aseptically manufactured drug products			
18.	To make working prescriptions for manufacturing of solutions for injection in ampoules			
19.	To select containers for solutions for injection with regard to physical and chemical properties of active ingredients			
20.	To control quality of sterile drug products in accordance with normative standards			
21.	To substantiate theoretically the choice of extraction method of medicinal plant material			
22.	To calculate mass of medicinal plant material and volume of extraction solvent for manufacturing of extraction preparations			
23.	To convert mass concentration of water-alcohol solutions into volume concentration and inversely, to determine concentration of water-alcohol solutions using alcoholmeter and densimeter			
24.	To control quality of extraction preparations in accordance with normative standards			
	Total sum of points			

FINAL CONTROL OF PRACTICAL TRAINING

To write the final control paper on production practical training are allowed students who have achieved the minimum score (72 points) for current activities and rendered a practical training report.

According to the practical training syllabus, students pass the final control in the last day of practical training for commission with supervisors form the University.

According to the educational plan, the form of final control on production practical training on industrial technology of drugs is graded credit.

LIST OF CONTROL QUESTIONS FOR FINAL CONTROL

1. General statements and definitions in pharmaceutical technology.
2. Dosage forms, requirements, classification.
3. Normative legislative documents for composition of drug products, quality of starting materials and finished products, manufacture, storage conditions and dispensing of drug products.
4. Manufacture of drug products according to the GMP guidelines.
5. Material balance.
6. Characteristics of powders, tablets, capsules, classification, pharmacopoeial requirements.
7. Production methods of tablets and capsules.
8. Quality control, packaging and labeling of solid preparations.
9. Dragee. Granules. Characteristics. Stages of manufacture. Nomenclature. Quality control.
10. New solid dosage forms. Classification. Characteristics.
11. Characteristics of liquid preparations as disperse systems, classification, requirements.
12. Solvents, classification, requirements. Water purified as a solvent. Pharmacopoeial requirements, receiving by distillation and non-distillation methods. Water purification equipment, operating mechanism. Quality control, storage conditions and shelf life.

13. Stages in the manufacture of aqueous and non-aqueous solutions.

14. Syrups. Classification. Production methods. Quality control. Nomenclature.

15. Dilution of ethanol to the required concentration. Alcoholometric tables. Manufacturing features of alcoholic solutions.

16. Rectification and recovery of ethanol.

17. Characteristics of suspensions and emulsions. Production methods. Manufacturing equipment.

18. Quality control of heterogeneous liquid preparations.

19. Semi-solid preparations for cutaneous application, classification, requirements.

20. Incorporation of active substances into the ointment bases. Manufacturing equipment for semi-solid preparations.

21. Process flow diagrams for manufacturing of semi-solid preparations. Quality control.

22. Rectal and vaginal preparations, classification and characteristics.

23. Production methods of suppositories, comparative characteristics. Equipment. Quality control.

24. Preparations that require aseptic manufacturing conditions.

25. Parenteral route of drug administration. Parenteral preparations, classification, requirements and characteristics.

26. Solvents for solutions for injection. Water for injection, receiving methods, storage conditions and quality control in accordance with normative documents.

27. Manufacturing stages of solutions for injection in ampoules.

28. Filtrating methods of solutions for injection; filtration materials and equipment.

29. Manufacturing features of solutions for injection that require special methods of purification.

30. Manufacture of solutions for injection with thermolabile substances.

31. Stability of solutions for injection; factors affecting the stability. Stabilization methods of solutions for injection.

32. Manufacture of solutions for injection that require addition of stabilizing agents (novocain, glucose, sodium and caffeine benzoate, ascorbic acid etc.).

33. Manufacturing features of oil solutions for injection.

34. Characteristics and classification of eye preparations.

35. Eye drops, requirements. Eye lotions, requirements and manufacture.

36. Characteristics, classification of eye semi-solid preparations, requirements and manufacturing features.

37. Quality control, packaging and labeling of eye preparations.

38. Extraction preparations from medicinal plant raw material. Extraction methods. Equipment.

39. Tinctures. Extracts. Extracts concentrates. Characteristics. Classification. Production methods. Process flow diagrams. Quality control. Nomenclature.

40. Neogalenic preparations. Characteristics. Manufacturing features. Quality control.

41. Purification of tinctures, extracts and neogalenic preparations. Equipment.

42. Quality control of extraction preparations.

Assessment criteria of final control on practical training:

Final control is conducted in written form and includes 15 tasks of II level that are evaluated in 2 points; 4 tasks of III-IV levels that are evaluated in 5 points, and 6 situational problems that are assessed on 5 points.

A maximum score that student can achieve in passing the final control is 80, a minimal score - 50.

№	Task	Date	Mark in points	Sign of supervisor
1.	Tests of II level			
2.	Tests of III-IV levels			
3.	Situational problems			
Total sum of points for final control				

REFERENCE AND ASSESSMENT OF STUDENT'S WORK DURING THE PRACTICAL TRAINING

From university _____

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MARK FOR PRACTICAL TRAINING

Points for:		Total points	Traditional mark	Date	Sign of supervisor
Practical skills	Final control				

Supervisor of practical training
from the Department

_____ _____

(sign) (full name)