MINISTRY OF HEALTH CARE OF UKRAINE
Danylo Halytsky Lviv National Medical University

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

Head of the Department: ***PhD, assoc. prof. S.B.Bilous***

PRODUCTION PRACTICAL TRAINING REPORT
on"Drug technology in pharmacy"

Full name of student _____

_____

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

Base of practical training_____

_____

Lviv-201__

Student _____
(full name)

undergoes practical training on ”Drug Technology in Pharmacy” on the base
_____
(name of pharmacy)

in_____
(city, region)

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

Supervisor of practical training from the Department _____
(post, full name, sign)

Supervisor of practical training from the Pharmacy _____

_____
(post, full name)

Student has arrived ___._____201 _ left ____._____201_.

Sign of responsible person _____

Place stamp here

GENERAL STATEMENTS

According to the academic curriculum, students of the Faculty of Pharmacy undergo the production practical training on "Drug Technology in Pharmacy" in the 4th course year after the end of summer examination period. Extent of practical training is 5 credits (3 week).

During the practical training students perform duties of a pharmacist in pharmacies that produce extemporaneous preparations. Students work for 6 hours daily during 15 days. Head of the pharmacy appoints immediate supervisor of the practical training.

Prior to the practical training students must be given instruction, syllabus, report on the practical training and referral to the practical training from the department. Arriving to the practical training, student must pass a safety training and refine a plan of practical training. During the practical training student must strictly comply with internal rules and regulations of the pharmacy.

Practical training report student writes in accordance with schedule of the training and recommendations of supervisors from university and pharmacy. Production practical training is assessed by 4-point grading scale.

Student who does not meet the requirements of practical training and gets the negative reference about the work or negative mark for the report may be expelled from the university

Purpose of the production practical training on "Drug Technology in Pharmacy" is to achieve basic objectives determined by professional education program on speciality 8.12020101 "Pharmacy" and serves for forming the content of the practical training.

Final objectives of the production practical training on "Drug Technology in Pharmacy" are:

- to deepen the knowledge gained in practical classes on "Drug Technology in Pharmacy", develop and improve practical skills and abilities required for adopting the independent decisions during the work in real production environment;
- to create the motivation in the future specialists systematically to refresh their knowledge, to get acquainted with the latest achievements in the pharmaceutical industry, to review scientific literature and apply the knowledge and skills into the practice.

Specific objectives of the practical training are:

- to get acquainted with organization of production process and pharmaceutical order in pharmacies that compound extemporaneous preparations;
- to learn nomenclature of active ingredients and excipients that are used for preparing of extemponeous formulations;
- to learn general statements of normative documents that regulate prescription, preparation and supplying of medicines;
- to understand features of work with toxic, potent and narcotic substances; check out single and daily doses and dispensing norms;
- to generalize rules of preparing powders that contain ingredients with different physical and chemical properties; liquid preparations by weight to volume method;

semi-solid preparations; suppositories; solutions for injection and infusion; eye preparations; drug products with antibiotics and for newborns;

- to learn features of filtration, stabilization and sterilization of solutions for injection and infusion in conditions of pharmacy;
- to summarize rules of packaging and dispensing of extemporaneous preparations.

As a result of the production practical training on "Drug Technology in Pharmacy", student should **be able to**:

- work with devices for dosing of ingredients with different physical and chemical properties;
- *in the manufacture of powders:* to keep rules of grinding and mixing of medicinal ingredients in accordance with their quantities, physical and chemical properties etc.
- *in the manufacture of liquid dosage forms*:
- to use measuring devices correctly and according to the intended purpose;
- to perform necessary calculations for checking out single and daily doses of toxic and potent ingredients;
- to determine total volume of solution, concentration of solid components; to calculate mass of active ingredients, excipients, and medicinal plant raw materials, volumes of concentrated solutions (if they are used in manufacture of liquid preparations), as well as volume of purified water needed for manufacture of liquid preparations by weight to volume method;
- to perform calculations for dilution of pharmacopeial liquids;
- to dissolve active ingredients and excipients; if necessary, to perform special technological operations: heating, complexating etc.;
- to filter solutions;
- to diperse or solubilize ingredients insoluble in water;
- to emulsify insoluble liquid phase, to make emulsion;
- to extract active ingredients from medicinal plant raw material;
- to work with small tools and equipment – for grinding, mixing, filtering, packaging, extracting.
- *in the manufacture of semi-solid preparations and suppositories*:
- to select ointment base in accordance with medical application of semi-solid preparation;
- to introduce active pharmaceutical ingredients into bases, considering their physical and chemical properties and medicinal application of preparation;
- to calculate mass of suppository base in accordance with prescription and production method of suppositories;
- to introduce active pharmaceutical ingredients into suppository mass;
- to prepare suppositories by different methods.
- *in the manufacture of sterile drugs:*
- to provide and follow aseptic conditions of manufacturing;
- to dissolve active ingredients and excipients needed for stabilization or preparing isotonic solution;

- to filter prepared solution and control it on particular matters;
- to prepare solutions for sterilization.
- *in the manufacture of different types of extemporaneous preparations*: to select packing materials depending on the type of dosage form and physical and chemical properties of ingredients, as well as to conduct organoleptic, question and written control of extemporaneous preparations.

During the practical training on "Drug Technology in Pharmacy" students write practical training reports , where they must accurately record and describe all types of performed work that is foreseen by program of the practical training. The immediate supervisor from the pharmacy checks out the reports every day and assesses the practical skills and abilities.

Student is required to note in the practical training report:

- layout and equipment in the assistant room;
- receiving of purified water, water for injection, quality control and storage conditions;
- technology of extemporaneous preparations (two dosage forms every day) in the prescribed order.

CONTENT OF PRODUCTION PRACTICAL TRAINING ON "DRUG TECHNOLOGY IN PHARMACY"

Production practical training on "Drug Technology in Pharmacy' is carried out in pharmacies that compounds extemporaneous preparations (88 hours) and at the Department of Drug Technology and Biopharmaceutics (final control).

During the production practical training students perform the job duties of a pharmacist who makes extemporaneous preparations. Changes in the order of tasks given in the plan of production practical training are allowed with the agreement of supervisor of the practical training.

PLAN OF THE PRACTICAL TRAINING

№	Topic	Days
1.	Passing the briefing on safety awareness, sanitary measures and pharmaceutical order. Analysis of structural subdivisions and a personnel staff of pharmacy (production areas of pharmacy, layout and equipment of workplaces, storage conditions for drug products and medical devices); requirements for sanitary and anti-epidemic regime of the pharmacy	1
2.	Preparing of combined powders with ingredients in different amounts and with different physical and chemical properties	1
3.	Preparing of combined powders with colour, colored, hard-grounded ingredients and with liquids	1
4.	Preparing of liquid preparation with dry ingredients and concentrated solutions by weight to volume method	1

5.	Preparing of non-aqueous solutions and drops for oral and external use	1
6.	Preparing of solutions with high molecular compounds and heterogeneous liquid preparations	1
7.	Preparing of homogeneous semi-solid preparations	1
8.	Preparing of heterogeneous semi-solid preparations	1
9.	Preparing of suppositories by pouring and rolling methods	1
10.	Preparing of solutions for injection without the stabilization and those that require the stabilization	1
11.	Preparing of isotonic solutions for infusion	1
12.	Preparing of eye preparations	1
13.	Preparing of preparations with antibiotics and for newborns	1
14.	Preparing of intrapharmacy products, including concentrated solutions and intermediate products	1
15.	Reception of prescriptions, control of doses and norms of toxic and potent substances, and compatibility of ingredients, processing for dispensing, and control of finished preparations. The rules of the dispensing of preparations with toxic, narcotic ingredients and precursors	1
	Total	15 days

List of practical skills and abilities that student should get during the practical training and their assessment in point grades

1. To use normative, informative and scientific literature to solve professional problems.
2. To check out appropriateness of prescriptions and determine compatibility of ingredients.
3. To perform necessary calculations for checking out single and daily doses of toxic and potent substances and their dispensing norms.
4. To work with prescription and hand balances; to weigh dry and viscous substances, liquids.
5. To prepare powders with ingredients with different physical and chemical properties; to use dosing and other labor saving tools.
6. To dose liquids by measuring devices and calibrate the empirical dropper.
7. To prepare aqueous solutions by weight to volume method.
8. To use special technological operations for improvement of active ingredients solubility.
9. To prepare solutions with non-aqueous solvents (ethanol, glycerol, oils).

10. To prepare drops, solutions with high molecular compounds, and colloids.
11. To prepare suspensions and emulsions.
12. To select appropriate stabilizing agents for heterogeneous systems.
13. To prepare acqueous extracts from medicinal plant raw material and with use of concentrated extracts.
14. To use labor saving tools (burettes, apparatus for preparing water extracts etc.);
15. To select ointment bases in accordance with medical application of semi-solid preparations.
16. To introduce active ingredients into the semi-solid preparations with consideration of their physical and chemical properties.
17. To prepare rectal, vaginal and urethral suppositories by pouring and rolling methods.
18. To provide and follow aseptic conditions for preparing sterile products. To prepare concentrated solutions for burette system.
19. To prepare solutions for injection with ingredients with different chemical properties.
20. To prepare eye preparations.
21. To dose antibiotics and prepare drug products with them.
22. To prepare drug products for newborns.
23. To choose packaging material in accordane with type of dosage form and physical and chemical properties of ingredients.
24. To prepare drug products for dispensing. To perform organoleptical, question, and writing control of extemporaneous preparations.

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 prepare it for dispensing, 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 PRACTICAL TRAINING ON
DRUG TECHNOLOGY IN PHARMACY

_____

(Full name of student)

No.	Practical skills and abilities	Date	Mark	Sign
1	To use normative documents, informative and scientific literature to solve practical tasks			
2	To check appropriateness of prescriptions and determine compatibility of ingredients. To perform necessary calculations for checking out single and daily doses of toxic and potent substances and their dispensing norms			
3	To work with prescription and hand balances; to weigh dry, viscous substances, and liquids			
4	To prepare powders with ingredients with different physical and chemical properties; to use dosing and other labor saving tools			
5	To dose liquids by measuring devices, calibrate empirical droppers. To prepare aqueous solutions by weight to volume method			
6	To prepare liquid preparations (with non-aqueous solvents, drops, solutions with high molecular compounds, and colloids)			
7	To select appropriate stabilizing agents for heterogeneous systems, and to prepare suspensions and emulsions. To prepare aqueous extracts from medicinal plant raw material and using concentrated extracts			
8	To prepare semi-solid preparations; rectal, vaginal and urethral suppositories by pouring and rolling methods			
9	To provide and follow aseptic conditions for preparing sterile products. To prepare concentrated solutions for burette system			
10	To prepare solutions for injection with ingredients with different chemical properties and to prepare eye preparations			
11	To prepare preparations with antibiotics and preparations for newborns			
12	To select packaging material in accordance with type of dosage form and physical and chemical properties of ingredients, to prepare drug products for dispensing. To perform organoleptical, question, and writing control of preparations prepared in pharmacy			
	Total sum of points			

LIST OF QUESTIONS FOR FINAL CONTROL

1. Normative documents that regulate rules of drugs production in pharmacies.
2. Dosing in formulated drug technology.
3. Checking out doses in dosage forms for oral administration.
4. Basic rules of compounding simple and combined powders with ingredients in different amounts and with different physical and chemical properties.
5. Triturations, their purpose and use.
6. Preparing of liquid preparations by weight to volume method.
7. Concentrated solutions for burette system: nomenclature, technology, quality control.
8. Calculation for dilution or strengthening of concentrated solutions.
9. Special cases in technology of solutions: silver nitrate, potassium permanganate, iodine, mercury diiodide, mercury dichloride, furacilline, ethacridine lactate, phenobarbital.
10. Standard pharmacopoeial liquids, their nomenclature.
11. Preparing of aqueous solutions of standard pharmacopoeial liquids.
12. Features of technology of solutions with non-aqueous solvents (glycerol, vegetable oils, ethanol etc.).
13. Dillution of ethanol.
14. High-molecular compounds, factors affecting stability of solutions with high-molecular substances.
15. Protected colloids, factors affecting stability of colloidal solutions.
16. Technology of solutions with starch, gelatin, pepsin, collargol, protargol and ichthyol.
17. Suspensions, methods of preparing.
18. Stabilization of suspensions, factors affecting sedimentation (kinetic) and aggregate (condensation) stability of suspensions.
19. Preparing of suspensions with hydrophilic and hydrophobic substances.
20. Emulsions for oral administration, their stabilization.
21. Selection of surface-active substances for stabilization of emulsions in accordance with value of hydrophilic-lipophilic balance.
22. Water extracts from medicinal plant raw material, factors affecting quality of water extracts.
23. Technology of infusions and decoctions from medicinal plant material containing essential oils, tanning substances, mucilages.
24. Technology of infusions and decoctions from plant materials containing alkaloids, anthracene derivatives and cardiac glycosides.
25. Use of concentrated extracts for preparing of water extracts.
26. Semi-solid preparations for topical use, classification, requirements.
27. Mechanism of drug absorption through the skin.
28. Bases for ointments.
29. Principles of introduction of drug substances into the ointment bases.
30. Preparing of homogeneous and heterogeneous ointments.
31. Preparations for vaginal and rectal use, classification and characteristics.

32. Characteristics of suppository bases, their influence on drug bioavailability.
33. Methods of preparing of suppositories.
34. Principles of introduction of aactive ingredients into suppository bases.
35. Calculation of bases for preparing the suppositories by different methods.
36. Solutions for parenteral administration, their classification and characteristics.
37. Pharmacopoeial requirements to parenteral preparations and their implementation in the pharmacies.
38. Features of technology of sodium bicarbonate solutions for parenteral use.
39. Features of technology of glucose solutions for parenteral use.
40. Features of technology of procaine solutions for parenteral use.
41. Features of technology of ascorbic acid solutions for parenteral use.
42. Eye preparations, their classification and characteristics.
43. Requirements to eye drops, thier implementation in pharmacies.
44. Prolongation of drug action in eye drops.
45. Eye semi-solid preparations, bases for the preparations.
46. Features of technology of dosage forms for newborns (dusting powders, liquid preparations for oral and topical use etc.).
47. Features of technology of dosage forms with antibiotics (powders, ointments, suppositories, eye drops etc.).
48. Classification of incompatibilities of drugs.
49. Ways to overcoming of incompatible combinations of drug substances in dosage forms.
50. Difficult prescriptions and ways for overcoming the technological problems.