NATIONAL UNIVERSITY OF PHARMACY

DEPARTMENT PHARMACEUTICAL TECHNOLOGY OF DRUGS

Workbook

for Work placement in Pharmacy based Technology of Drugs

with methodical recommendations

for English students of higher education
of “226 Pharmacy, industrial pharmacy” specialty

Year _____group_____

_____

(surname, name)

Place of practical training: _____

_____

(No. of the chemist’s shop, address, telephone)

Time of practical training: from _____20___ year to _____20__ year.

Leader of pharmacy establishment:

_____

(surname, name)

Leader of practical training from a department:

_____

(surname, name)

Kharkiv-2023

UDC 615.014.2:371.388
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Approved by the Central Methodological Commission

of the National University of Pharmacy (protocol №1 from 01.09.2023)

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H Workbook for Work placement in Pharmacy based Technology of Drugs with methodical recommendations for English students of higher education of “226 Pharmacy, industrial pharmacy” specialty / L. I. Vyshnevska, N. P. Polovko, S. V. Oliinyk, M. V. Buryak. – Kh., 2023. – 58 p.

The employers of Department pharmaceutical technology of drugs compose a workbook for Work placement in Pharmacy based Technology of Drugs with methodical recommendations for English students of higher education of “226 Pharmacy, industrial pharmacy” specialty, passing practical training in pharmaceutical technology of drugs on the base of chemist’s shops, and for leaders of practical training from a department and pharmacy establishment. It contains the maintenance of practical training; duties of students of higher education and leaders from a department and pharmacy establishment; requirements to conduction of current documentation; the list of practical abilities and skills, the order of leadthrough of current and semester control, the list of literature. This edition will be instrumental in the high-quality passing of practical training in chemist’s technology of drugs.

ISBN

INTRODUCTION

This workbook for Work placement in Pharmacy based Technology of Drugs with methodological recommendations is composed according to the curriculum, to the “Statute about practical training for students of higher schools” and to the contents of pharmacist qualification characteristics.

Aim of practical training in chemist’s technology of drugs is to consolidate theoretical knowledge, to broaden practical abilities and to acquire practical skills in questions of extemporaneous medicines preparation, their quality control and registration for dispensing.

According to the curriculum, practical training in chemist’s technology of drugs is conducted during 3 weeks (15 working days) for foreign 5^{th}-year students of “226 Pharmacy, industrial pharmacy” specialty.

Practical training is conducted at the chemist’s shops, which satisfy the requirements to the bases for practical training and occupy production activity. Students undergo practical training at the workplace of pharmacist on preparation of extemporaneous medicines (EM) and at the workplace of pharmacist on preparation of intrapharmacy products (IPP) and medicines registration for dispensing.

STUDENTS’ TRAINING MANAGEMENT

Responsibility for organization and implementation of practical training at the chemist’s shop is placed on chemist’s shop manager or his assistant.

The direct management over students’ training at certain allotments of work is placed on highly qualified specialists with sufficient operational experience (according to the order of chemist’s shop manager).

Duties of the chemist’s shop manager:

- to check the presence of students’ assignment, journal of practical training and workbook with methodological recommendations (hereinafter referred to as “workbook”);
- it is necessary to mark the date of student’s arrival to the practice in the journal of practical training, to seal and to sign it;
- to acquaint students with production premises and the staff of the chemist’s shop; to provide with instructions on labour protection, safety measures and rules of internal order:
- by means of order at the chemist’s shop, to assign the experienced specialists as students on-site practical training managers;
- on finishing the practice, to check the workbook and to certify it with personal signature

and seal of the chemist's shop;

~ in the journal of practical training, to sign and to certify with seal the reference of student's work during practical training, to mark the date of student's departure from the practice, to seal and to sign it.

Duties of on-site practical training manager:

- to instruct and to acquaint students with work organization at the concrete workplaces, with the situation of medicinal and auxiliary medicinal substances and materials, devices and apparatus which are used in preparation of medicines, with the rules of labour protection and safety measures;
- to follow the observance of pharmaceutical order and sanitary requirements by students; to implement the constant control over students work, to help them to carry out all tasks correctly on-site;
- before extemporaneous preparation of medicines by students, to check their calculations, to control the correctness of conducting the technological operations;
- to control timeliness of workbook filling, to make appropriate remarks, if necessary;
- in the journal of practical training, to mark the fulfillment of practice passing schedule every day;
- on finishing of practice, to compose the reference of student's work in the journal of practical training, where it is necessary to characterize theoretical knowledge and practical skills of student and to evaluate his/her work during the practice.

Duties of the student:

- ➢ to receive the assignment and journal of practical training in the practice department;
- ➢ to be instructed at the technology of drugs department about passing of practice, to get this workbook;
- ➢ to arrive promptly to the chemist's shop by the beginning of the practice;
- ➢ to show the assignment, journal of practical training and this workbook to the chemist's shop manager and to proceed to the passing of the practice;
- ➢ to submit to the effective rules of internal order at the chemist's shop, to follow the operating schedule;
- ➢ to learn and obey the rules of labour protection and safety measures, to keep to the pharmaceutical order and sanitary requirements;
- ➢ to be responsible for performed work equally with full-time workers of the chemist's shop;
- ➢ to carry out the tasks, which are provided for practice program, fully;

- to keep the workbook and to give it daily to the direct on-site practice manager for checking.

CONTENTS OF PRACTICAL TRAINING

Module 1. General knowledge of the chemist's shop. Preparation of non-sterile and sterile medicines and intrapharmacy products.

Semantic module 1. General knowledge of the chemist's shop. Preparation of non-sterile and sterile medicines and intrapharmacy products.

Description of work	Number of days
Theme 1. Knowledge of chemist's shop's premises and rooms. Analysis of regulations requirements to the premises of the chemist's shop observance.	2
On the pharmacist's working place of extemporaneous medicines preparation: **Theme 2.** Analysis of regulations requirements to the productive activity of the chemist's shop observance. Preparation of solid extemporaneous medicinal forms (EMF). **Theme 3.** Preparation of liquid EMF. **Theme 4.** Preparation of semi-solid EMF. **Theme 5.** Preparation of sterile and aseptic EMF.	9
On the pharmacist's working place of intrapharmacy products preparation and registration medicines for dispensing: **Theme 6.** Analysis of regulations requirements to intrapharmacy products preparation observance. Preparation of intrapharmacy products (IPP), packing, re-handling and labeling of medicines.	3
Theme 7. Execution of report documents.	1
Total number of days:	15

REPORT DOCUMENTATION

1. THE WORKBOOK

(given at the department)

During practical training, in their workbooks, students must perform the following tasks:

Task 1. To fill in the table "Regulations requirements to the productive activity of the chemist's shop" with the detailed answers on formulated questions. It is necessary to expound the essence of the requirement and to point the document, by which it is regulated, in the column "Requirements".

To submit in the form of the photo and video materials:

– description of the pharmacist's working place at the assistance room and of the working place at the aseptic block,

– description of the pharmacist's working place on packing and intrapharmacy products,

– description of pharmacist's working place on quality control,

– description of the labour-saving tools, which are used in preparation of EMF and IPP,

– filled labels for medicines for internal and external usage, for injections and for packing.

Task 2. To describe technology of EMF, which were received at the chemist's shop during practice.

Task 3. To compose s technological instruction for EMF.

Task 4. To study the journals, in which data on preparation of EMF, IPP, packing and rehandling of medicines are registered. In the form of supplement, to give copies of the cover pages and one page of each journal, in which to describe 1-2 examples of their filling by you.

2. REPORT ON PRACTICE PASSING

(is written by a student)

A student based on fulfilled practice program, his own observations, writes report and **the practical training managers do not certify it**.

Reflecting the whole work for a period of practical training, the student must show the ability to analyze the done work and the enough qualified preparation in chemist's technology of drugs.

In the report there must be reflected:

1. Description of conditions and settings, in which student's training passed;
2. Order of practical training passing, its contents in each;
3. Shortcomings of the production process (equipment, organization, control), their reasons;
4. Discrepancies between practice and theory, which have been revealed by the student as a result of practice passing, their reasons and his own point of view on possibility of their elimination;
5. In conclusion, the student must evaluate the practical training, its positive and negative sides.

Report should be formatted on the separate sheets of paper according to the mentioned headings.

3. JOURNAL OF PRACTICAL TRAINING

(given by the practice department)

On the first day of practical training, the date of the student's arrival is marked on the second page of the journal; it is certified with a seal and a signature of the chemist's shop manager. On the last day of practical training the date of the student's departure from the

chemist's shop is marked, it is also certified with a seal and a signature of the chemist's shop manager.

Furthermore, the following points are completed in the journal:

– 2 – the actual calendar schedule of practice passing, which is signed by the on-site practical training manager;

– 3 – reference about student's work (testimonial) by the practical training manager from the chemist's shop – certified with the chemist's shop manager's signature and the chemist's shop's seal;

– 5 – the other kinds of works, which were performed by the student in addition to the program, are indicated.

After finishing of the practical training, the student must give to the department's lecturer the filled in and formalized workbook, report and journal of practical training.

CONTROL OF PRACTICAL TRAINING PASSING

Passing of practical training is estimated on 100-balls rating system of students' evaluation (61-100 balls).

Current module control of practical training passing (35-60 balls) includes the mark on formalization of the report documentation and completeness of fulfillment of tasks, which are stipulated by the program of the practice. At the same time, testimonial, given by the practical training manager from the chemist's shop, and the mark, put by him for practical training passing, is taken into account.

Semester control (25-40 balls) is conducted at the department in the form of computer testing and solution of situational tasks, which are composed in accordance to the list of practical abilities and skills (supplement 1).

Total module control is conducted after finishing of practical training during **first 10 days** of the next semester.

Module 1. General knowledge of the chemist's shop. Preparation of non-sterile and sterile medicines and intrapharmacy products.

Semantic module 1. General knowledge of the chemist's shop. Preparation of non-sterile and sterile medicines and intrapharmacy products.

Task 1. Fill in the table, give the detailed answers on the formulated questions with minute indications of requirements and broadened explanations (comments).

REGULATIONS REQUIREMENTS IN THE EXERCISE OF THE PRODUCTIVE ACTIVITY OF THE CHEMIST'S SHOP*

Question	Requirements	Yes	No	Comments
Theme 1. Knowledge of chemist's shop's premises and rooms. Analysis of regulations requirements to the premises and equipment of the chemist's shop observance.				
I. Description of the chemist's shop				
1. Is the chemist's shop situated in the special building or in the adapted premises?				Area:
2. Does the chemist's shop serve any medioprophylactic?				Specify the medioprophylactic: 1._____ _____ _____ _____ 2._____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

*In the absence of the productive activity at the chemist's shop the table is filled in on the basis of study of TND of MH of Ukraine requirements.

Question	Requirements	Yes	No	Comments
3. Does the chemist's shop occupy with the productive activity?				License:
4. Is there a sterile (aseptic) zone at the chemist's shop?				From which rooms does it consist of:
5. Which departments are there at the chemist's shop?				
6. What is the staff of the chemist's shop? Positions, number of employees	6.1. in preparation of EM: 6.2. in preparation of sterile EM: 6.3. in packing and in preparation of: 6.4. in supplement of the assistant room with the necessary ingredients: 6.5. in conducting of intra-pharmacy control: 6.6. in receiving of prescriptions and dispensing of medicines:			
7. Does a visiting medical doctor work at the chemist's shop?				Indicate his specialization:

Question	Requirements	Yes	No	Comments
II. Premises and equipment				
Give the schematic plan of the chemist's shop, assistant room and aseptic block*				

* Assistant room and aseptic block can be introduced in the form of photo and video materials

Question	Requirements	Yes	No	Comments
8. Which productive premises are there at the chemist's shop?	*Assistant room, aseptic block (or sterile zone), storage room etc.* - - -			
9. Do the premises correspond to the requirements?	Required area: -hall for visitors, -assistant room, -washhouse room, - - - -			Actual area: - - - - - - -

10. Enumerate the productive equipment which is used in preparation of non-sterile medicines*:

Powders: _____

_____

_____

Medicinal herbal teas: _____

_____

_____

Liquid medicinal forms: _____

_____

_____

_____

_____

Ointments, pastes, gels: _____

_____

_____

_____

Suppositories: _____

_____

_____

*Tools and equipment can be introduced in the form of photo and video materials

Question	Requirements	Yes	No	Comments
11. Enumerate the productive equipment which is used in preparation of medicines in aseptic conditions*:_____				
12. How often is the sanitization of the equipment conducted?				
13. In there in the productive premises the equipment which is not required to the works under way?				
14. Are the air-conditioners used at the premises?				Air exchange:

* Tools and equipment can be introduced in the form of photo and video materials

Question	Requirements	Yes	No	Comments
15. Are the working places at the hall for visitors equipped with means of protection of the staff from respiratory infection?				From which material:
16. Which cleaning of the premises is conducted at the chemist's shop?	*-wet* *-dry*			How often is the cleaning conducted?
17. Which detergents are used when cleaning of the premises?	Which document permits their usage:			
18. Which disinfectants are used when cleaning of the premises?	Which document permits their usage:			
19. How is the disinfection of the staff's hands provided?				Which disinfectant is used:

Question	Requirements	Yes	No	Comments
III. Normative documents, which regulate the work of the chemist's shop				
20. Specify the necessary normative documentation which regulate productive activity of the chemist's shop.	-laws -resolutions -Pharmacopoeias -orders -instructions -others			Specify the other available types of ND:

Give the numbers of normative documentation, dates of adoption and names:

Laws: 1. _____

_____

2. _____

_____

Resolutions: 1. _____

_____

_____

_____

_____

Pharmacopoeias: _____

_____

Orders, instructions (numbers and dated of adoption): _____

_____

_____

_____

_____

_____

_____

_____

_____

Others: _____

_____

_____

_____

_____

Question	Requirements	Yes	No	Comments
21. Specify documentation which regulates the rules of preparation of *non-sterile medicines*	Specify name and number of the documents, point the items in which requirements are stated			Which requirements are not followed and why?
22. Specify documentation which regulates the rules of preparation of *sterile medicines*				
23. Specify documentation which regulates the order of carrying out *of intrapharmacy control of medicines*				
24. Specify documentation which regulates *sanitary requirements to the premises, equipment, staff*				

Question	Requirements	Yes	No	Comments
25. Specify documentation which regulates *the rules of prescribing and receiving of the prescriptions*				
26. Specify documentation which regulates *requirements to the staff*				
27. Specify documentation which regulates *requirements to the premises and equipment*				
28. Specify documentation which regulates *obtaining of intra-pharmacy products, packing and rehandling of medicines*				
29. Specify documentation which regulates *the rules of registration for dispensing of the medicines*				
30. Specify documentation which regulates *the rules of distribution of the medicines* from the chemist's shop				

Question	Requirements	Yes	No	Comments
IV. Terminology (give the definitions)				
31. Give the definition of the term “extemporaneous medicine”				
32. Give the definition of the term “medicine”				
33. Give the definition of the term “active ingredient” (substance)				
34. Give the definition of the term “medicinal form”				
35. Give the definition of the term “auxiliary substances”				
36. Give the definition of the term “medicine, made for future use”				
V. Medicinal and auxiliary substances				
37. Are only the substances of Pharmacopoeial quality used for preparation of medicines ?	Which document regulates it?			

Question	Requirements	Yes	No	Comments
38. Are the ingredients of non-Pharmacopoeial quality used for preparation of drugs?				If yes, specify the types f TND which regulates their quality
39. Should the quality certificates for all medicinal and auxiliary substances be at the chemist's shop?				
40. Should the results of analysis of all substances from analytical laboratory be at the chemist's shop?				
41. Which information should be on all glass bottles with medicinal substances?	According to order №_____ there must be specified: - name of the substance - country - manufacturer - _____ - _____ - _____ - _____ - signature _____ whose signature?			Additionally there are specified : 1. for substances which contain moisture – _____ _____ 2. for standard Pharmacopoeial liquids – _____ _____ _____ 3. for substances which contain glycosides – _____ _____ _____
42. Is it allowed to use readymade medicines for preparation of EM?	- non-sterile EM for external use - non-sterile EM for internal use - sterile EM			Какими документами это регламентируется?

Question	Requirements	Yes	No	Comments
43. Is the possibility of impact of auxiliary ingredients of factorial medicine on the quality of prepared from them EM taken into account?				
44. If the factorial medicines are used, than, after the factorial packing opening, is it marked with the label with the shelf-life after its opening?				
VI. Work with prescriptions on EM				
45. Are the rules of prescribing of received at the chemist's shop prescriptions followed?	Specify the requirements			
46. Are the doses of strong-effective and poisonous substances checked when receiving the prescriptions?	Who conducts the check of doses? (position of the employee)			Where are the calculation made?
47. Is the compatibility of the ingredients checked in the prescription?	Who conducts the check? (position of the employee)			Which sources (literature, the internet, computer data) are used?
48. What does the provisor do when detection of incompatibility in the prescription?				

Question	Requirements	Yes	No	Comments
49. Are the received prescriptions for preparation of EM registered?				Specify the journal for registration and person, who provides registration:
50. Are there any notes or calculations made on the prescriptions?				
51. Are the prescriptions given to the assistant room immediately for preparation?				
52. Is there any treatment of the prescriptions made with the purpose of their disinfection?	- before giving prescriptions to the assistant room - before giving the prescription to the aseptic block			
VII. Documentation when preparation of medicines				
53. Is the documentation in paper or electronic form?				

Specify the names and settings of the computer programs: _____

_____

_____

_____

_____

_____

_____

Question	Requirements	Comments
54. Specify the type of the necessary documentation when preparing of EM:		
– enumerate **general instructions** for preparation of EM	1. _____ _____ 2. _____ _____ _____ _____ _____ _____ _____	
– **productive notes** (journals, etc.) for registration of *EM* technological process		Who is responsible for their keeping and storing?
– **technological instructions** for medicines, *made for the future use*		
– **productive notes** (journals, etc.) for registration of technological process of the *medicines made for the future use*		Who is responsible for their keeping and storing?
55. Specify conditions and shelf-life of prescriptions and requests of medicoprophilactic institutions at the chemist's shop		

Question	Requirements	Comments
Themes 2-5. *Analysis of regulations requirements to the productive activity of the chemist's shop observance. Preparation of solid, liquid, soft, sterile and aseptic EMF.*		
VIII. Preparation of medicines in conditions of the chemist's shop		
56. Sequence of technological process when preparation of EM:		
1) Check of correctness of prescription form execution, compatibility of ingredients and doses		*Who checks:*
2) Calculations of quantity of active and auxiliary substances		*Who makes calculations:*
3) Implementation of sanitary preparing of the staff		*What clothes:*
4) Implementation of sanitary preparing of preparation zone and equipment		*How is the zone cleaned:*
5) How many prescriptions can be prepared simultaneously on one working place?		
6) Selection of the proper packing	*Which documents are followed when selecting of packing for EM?*	*From which factors does the choice of packing material depend on?*
7) Selection of auxiliary materials and equipment for preparation of EM	*Which rules are followed?*	

Question	Requirements	Comments
8) Grounds of EM technology	*Which documents or literature sources are followed at the chemist's shop when grounding EM technology?*	
9) Filling in of WCP	*Which documents regulate implementation of written control?*	*Who and when fills in WCP?*
10) Intrapharmacy control	*Which documents regulate implementation of intrapharmacy control?*	*Obligatory kinds of control (also specify who conducts):* - - - - - *Selective kinds of control:* - - -
11) Labeling of EM	*Which documents regulate?*	*Who conducts labeling?*
12) Cleaning of the working place and equipment after preparation of EM		*Who conducts?*
13) Control when dispensing		*Who conducts?*

Question	Requirements	Comments
57. EM technology according to the general rules, which are stated in SPU, orders of MH of Ukraine N. 626, 391, 197		
POWDERS		
- stages of powders preparation	_____ _____ _____	
- rules of mixing of powder ingredients	- -	Which physicochemical properties of substances re necessary to take into account? _____ _____ _____
- which packing is used for dispensing of powders?		
SOLUTIONS, SUSPENSIONS, EMULSIONS		
- stages of liquid EM preparation	_____ _____ _____	
- which rules of Liquid EM preparation should be taken into account?	– aqueous solutions:_____ _____ _____ _____ _____ –non-aqueous solutions:_____ _____ _____ – suspensions:_____ _____ _____ _____ – emulsions:_____ _____ _____ _____	

Question	Requirements	Comments
- which substances can be used as stabilizers and emulsifiers?		
- is the sedimentation acceptable in suspen-sions?		
- is the exfoliation of emulsion acceptable?		
- which bottles are used for packing?	– of suspensions: – of emulsions:	Which auxiliary label should be on the packing?
OINTMENTS AND PASTES		
- stages of ointments preparation		
- rules of ointments preparation		
- how is the homogeneity of ointments and pastes checked?		
- which packing is used for dispensing of oint-ments? - which auxiliary label should be on the pack-ing?		

Question	Requirements	Comments
SUPPOSITORIES		
- stages of suppositories preparation		
- rules of suppositories preparation		
- is the suppository mass weighed?		
- are the ready suppositories weighed?		
- how is the quality of the suppositories evaluated?		
- which packing is used for dispensing of suppositories?		
- which auxiliary label should be on the packing?		
EM which are prepared in the aseptic conditions		
- specify the medicinal forms which are prepared in the aseptic conditions		

Question	Requirements	Comments
- which sort of medicinal and auxiliary substances is used for preparation of sterile EM?		
- specify the sequence of technology of solutions for injections		
- which filter material is used?		
- which method of sterilization is used for EM?		
- which kinds of control are used for:	- solutions for injections: - EM for newborn:	
- which packing is used for dispensing of sterile EM?		
- which auxiliary label should be on the packing?		

Question	Requirements	Yes	No	Comments
IX. Quality control				
58. Is it obligatory to conduct the written control?				Who conducts:
59. Is it obligatory to conduct the polling control?				Who conducts:
60. Is it obligatory to conduct the physical control?				Is the deviation of EM's volume/mass from the required acceptable?
61. Is it obligatory to conduct the visual control?	Which indicators are checked for: - powders			Who conducts:
	- solutions			
	- suspensions			
	- emulsions			
	- ointments, pastes			
	- suppositories			
	- solutions for injections			
	- eye drops			
	- child's medicines			

Question	Requirements	Yes	No	Comments
62. Is it obligatory to conduct the chemical control?				Who conducts:
63. Is it obligatory to conduct the control of EM when dispensing?				Who conducts:
64. Do the procedures of study and correction of mistakes, that appear when preparation of medicines, exist?				
X. Stability of the medicines which are prepared in conditions of the chemist's shop				
65. Specify the factors which influence on stability of the prepared EM				
66. Specify the conditions of storage of the prepared EM				
67. Is the shelf life specified on the EM labels?	Which document regulates:			
68. How long is the shelf life of: – EM? – medicines, made for the future use?				

Question	Requirements	Yes	No	Comments
XI. Written control passport				
69. Which entries should be made in the written control passport (WCP)?	According to _____ it should be specified in WCP: - _____ - _____ - _____ _____ - _____ _____ the signatures of the workers should be put: - _____ - _____ - _____			
70. Should the entry in the WCP reflect the technology (order of ingredients' introducing)?				
71. On which language is the entry in the front side of WCP made?				
72. When is the filling in of the front side of WCP conducted?				Who conducts:
73. Which data should be written in WCP when using of semi-finished products or concentrates?	According to _____ it should be specified in WCP: – – –			
74. Are the coefficients, used in calculations, specified in WCP?				
75. During which term is WCP stored at the chemist's shop?				
XII. Guidelines for the patients				
76. Which guidelines should be given to the patients when dispensing of EM?	- about right usage of the medicine? - about its storage? - about the signs of instability of the medicine?			

Question	Requirements	Yes	No	Comments
Theme 6. *Analysis of regulations requirements to intrapharmacy products preparation observance. Preparation of intrapharmacy products (IPP), packing, rehandling and labeling of medicines.*				
XIII. Intrapharmacy products (IPP)				
77. Are the IPP produced at the chemist's shop?	Nomenclature: _____			
78. Is there the separate premise for IPP preparation?*	- room? - working place?			

* Describe the premises and equipment or introduce them in the form of photo and video materials

Question	Requirements	Yes	No	Comments
79. Are the labour-saving tools used when preparing of IPP?	List*: 1. 2.			
80. Which documents regulate preparation of IPP?	- production notes - technological instructions - other			
81. In which form are these documents introduced? Do the pharmacists know how to obtain the admittance to them?	- printed? - electronic?			

* Describe the labour-saving tools and give their photo

Question	Requirements	Yes	No	Comments
82. Are there at the chemist's shop the journals for IPP registration? Who, and in which moment of IPP preparation, makes entries in these journals?	Names and forms of the journals * 1. 2. 3.			
83. How is the IPP preparation controlled?				Who controls:

* Give the photocopies and photos of the forms of the journals

Question	Requirements	Yes	No	Comments
XIV. Packing, rehandling				
84. Is there at the chemist's shop the necessary documentation which regulates rehandling?	Specify the names and numbers of the documents:			
	Specify the requirements:			Are the requirements observed?

Question	Requirements	Yes	No	Comments
85. Who has the right to make rehandling?				
86. Are the parameters of humidity and temperature observed at the premise of rehandling?				
87. Give the definition of the term “rehandling”				
88. Give the definition of the term “container”				
89. Requirements to rehandling	1. Is the integrity of the original packing checked before rehandling?			
	2. Are there the data about medicines sensitiveness to the humidity, light or oxygen of air?			
	3. Do the containers provide protection of light-sensitive medicines at level of the original packing?			

Question	Requirements	Yes	No	Comments
	4. Are the conditions of medicines storage in containers known? If they are unknown, than what conditions should be?			
	5. How the label is formated?			
	6. How long is the term of the shelf-life of medicines after their rehandling?			
90. Which the documentation, which confirms the observance of all rules of rehandling, is kept?				

Question	Requirements	Yes	No	Comments
XV. Labeling of EM and IPP				
91. Which documentation regulates labeling of prepared medicines?	- EM: - IPP:			
92. Text of the main label for EM contains the following signs and information: 1 2 3				
93. Text of the main label for IPP contains the following signs and information: 1 2 3 4				

Question	Requirements	Comments
94. How is the labeling of the prepared EM made?*:	Main labels: - of powders	Auxiliary labels:
	- of solutions, suspensions, emulsions	
	- of ointments, suppositories	

* Illustrate the observation of these requirements with the filled in labels. The registered medicines can be introduced in the form of photo and video materials.

Question	Requirements	Comments
	- of solutions for injections	
	- of eye drops	
	- of child’s medicines	

Question	Requirements	Comments
95. How is the labeling of IPP made*:	- of concentrated solutions	
	- of semi-finished products	
	- of medicines made for the future use	

* Illustrate the observation of these requirements with the filled in labels. The registered medicines can be introduced in the form of photo and video materials.

Task 2. Describe technology of EM, which arrived at the chemist's shop during the practice.

Rp.:	The given medicine is:

Technology: _____

WCP (reverse side)	WCP (front side)

registration for dispensing: _____

Rp.:	The given medicine is:

Technology: _____

WCP (reverse side)	WCP (front side)

Registration for dispensing:_____

Rp.:	The given medicine is:

Technology: _____

WCP (reverse side)	WCP (front side)

Registration for dispensing:_____

Rp.:	The given medicine is:

Technology: _____

WCP (reverse side)	WCP (front side)

Registration for dispensing: _____

Rp.:	The given medicine is:

Technology: _____

WCP (reverse side)	WCP (front side)

Registration for dispensing:_____

Rp.:	The given medicine is:

Technology: _____

WCP (reverse side)	WCP (front side)

Registration for dispensing:_____

Task 3. Study the structure of the technological instruction (SPU, add. 2, order of MH of Ukraine # 391). Make the technological instruction for one the EM, which arrived at the chemist's shop during the practice.

Title page

Approve:

(Name of EM)

Endorsed by:

Composition: _____

_____

_____

_____

_____

_____

_____

Description: _____

_____

_____

_____

active substances _____

_____

_____

_____

_____

_____

_____

_____

_____

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_____

_____

auxiliary substances _____

_____

_____

_____

_____

_____

_____

Compatibility of the prescription components _____

_____

_____

_____

Calculations (WCP, reverse side)

Grounding of technology

Equipment

Safety rules

Technology

Packing

WCP (front side)

Quality control

Registration for dispensing (labeling)

Conditions and term of storage

Usage of the medicine (recommendations for the patients)

Task 4. Study the journals in which data about preparation of EM, and IPP, packing and re-handling of medicines are registered. Describe 1-2 examples of filling in of each journal[*].

[*] Draw the forms of journals and fill them in. Or give the photocopies of the title page and the last filled in page of each journal and continue filling in of the photocopy with your own examples.

LIST OF THE PRACTICAL ABILITIES AND SKILLS IN PHARMACEUTICAL TECHNOLOGY OF DRUGS

1. To know the normative base, which regulates the productive activity of the chemist's shops, to be able to work with it.
2. To know and to analyze the contents of requirements of TND in organization, conducting and control of productive process at the chemist's shop.
3. To be able to implement the requirements of TND into the practical activity of the chemist's shop.
4. To check single and daily doses of poisonous, narcotic, strong-effective substances and norms of delivery for narcotic substances and substances equated to them.
5. To identify physical, chemical and pharmacological incompatibilities in prescriptions.

POWDERS

6. To calculate the quantity of medicinal substances for preparation of powders.
7. To carry out the main technological operations (weighing, grinding, mixing, dosing) when preparing powders.
8. To use the labour-saving tools for mixing and dosing of powders.
9. To choose the packing material according to the properties of ingredients and to regaiter medicine for dispensing.

LIQUID MEDICINAL FORMS

10. To calculate the quantity of water and medicinal substances for preparation of concentrated solutions.
11. To carry out the main technological operations when preparing concentrated solutions (Weighing, measuring, dissolving, filtrating). To use the burette system.
12. To calculate the quantity of medicinal substances, concentrated solutions and water for preparation of solutions, which contain up to 3 5 and more than 3 % of dry substances.
13. To carry out the main technological operations when preparing liquid medicinal forms with the use of concentrated solutions and dry substances (weighing, measuring, dissolving, straining).
14. To calculate the quantity of water, medicinal and auxiliary substances for preparation of drops.
15. To calculate the quantity of water and Pharmacopoeial liquids according to the way of their prescribing.
16. To calculate the quantity of alcohol and water for obtaining of alcohol of the needed concentration (with the use of the formula of dilution and tables).
17. To carry out the main technological operations when preparing non-aqueous solutions (weighing, measuring, heating, dissolving, straining).
18. To choose and to ground the optimal technology of solutions HMC and protected colloids.
19. To carry out the main technological operations when preparing solutions of HMC and protected colloids (weighing, measuring, heating, dissolving, straining).
20. To calculate the quantity of medicinal substances and solvent when preparing

suspensions and quantity of stabilizer when preparing suspensions with hydrophobic substances.
21. To carry out the main technological operations when preparing suspensions (weighing, grinding, mixing, measuring).
22. To choose the suitable stabilizer according to the physicochemical properties of ingredients of emulsion.
23. To calculate the quantity of oil, emulsifier and water for preparation of emulsion.
24. To choose and to ground the way of emulsion preparation according to the nature of emulsifier.
25. To carry out the main technological operations when preparing oily emulsion (weighing, measuring, dissolving, heating, mixing, emulsifying, straining).
26. To introduce medicinal substances with different physicochemical properties into the composition of emulsion.
27. To calculate the quantity of medicinal plant raw material or extracts-concentrates and water for preparation of infusions and decoctions.
28. To carry out the main technological operations when preparing infusions and decoctions (grinding, sifting, weighing, measuring, extracting, cooling, straining, brining up to the volume).
29. To use the labour-saving tools when preparing of water extractions (infusers, etc.).
30. To introduce medicinal substances with different physicochemical properties into the composition of water extracts.

LINIMENTS, OINTMENTS, SUPPOSITORIES

31. To calculate the percentage content of medicinal substances with different physicochemical properties, which are contained in ointments, and quantity of auxiliary substances for preparation of homogeneous and heterogeneous ointments.
32. To carry the main technological operations when preparing liniments and ointments of different types of dispersed system (weighing, measuring, mixing, grinding, dissolving, emulsifying).
33. To calculate the quantity of medicinal and auxiliary substances for preparation of suppositories.
34. To choose and to ground the optimal variant of technology according to the properties of ingredients, which are contained in the prescription, and equipment, which is used for it.
35. To carry out the main technological operations when preparing suppositories by the rolling or casting method (weighing, grinding, dissolving, mixing, emulsifying, dosing, rolling, melting, pouring into the forms, cooling, pulling out from the forms).
36. To use the labour-saving tools for preparation of suppositories by the rolling or casting method (pill machine, machine for grinding of Cacao butter, device for heating and melting of the bases, forms for pouring etc.).

ASEPTIC MEDICINAL FORMS

37. To calculate the quantity of medicinal and auxiliary substances for preparation of solutions for injections.
38. To choose stabilizer and to ground the necessity of stabilization of medicinal substance in solutions for injections.

39. To calculate the isotonic concentrations of solutions for injections by the different method.
40. To choose the optimal variant of technology of solutions for injections according to the physicochemical properties of ingredients and the available equipment.
41. To choose and to ground the rational way of preparation of suspensions for injections or solutions of thermolabile substances.
42. To carry out the main technological operations when preparing solutions for injections (weighing, dissolving, filtrating, control of mechanical admixtures absence, hermetic corking up, registration for sterilizing, sterilizing).
43. To calculate the quantity of medicinal and auxiliary substances for preparation of eye medicines and medicines with antibiotics
44. To calculate the isotonic concentration of eye drops, washings and lotions.
45. To choose and to ground the optimal variant of technology of eye medicines according to the properties of ingredients and the available equipment.
46. To carry out the main technological operations when preparing eye medicines and medicines with antibiotics (weighing, measuring, dissolving, filtrating, grinding, mixing, melting, sterilizing, rolling, molding, dividing into doses etc.).
47. To choose packing material according to the type of medicinal form and physicochemical properties of ingredients.
48. To use the labour-saving tools in the process of preparation of sterile medicines (apparatus for filtration, machine for closing of aluminum corks, apparatus for sterilization, drying box etc.

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Робочий зошит виробничої практики з методичними рекомендаціями складено співробітниками кафедри аптечної технології ліків для іноземних студентів спеціальності «226 Фармація, промислова фармація», які проходять виробничу фармацевтичну практику з технології ліків аптечного виробництва на базі аптек, а також для керівників практики від кафедри і аптек. В ньому відображено зміст практики; обов'язки студентів і керівників практики від аптек; вимоги до ведення звітної документації; перелік практичних умінь та навичок, порядок проведення поточного та семестрового контролів та список літератури. Дане видання сприятиме якісному проходженню студентами виробничої практики з технології ліків аптечного виробництва.

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РОБОЧИЙ ЗОШИТ ВИРОБНИЧОЇ ФАРМАЦЕВТИЧНОЇ ПРАКТИКИ З ТЕХНОЛОГІЇ ЛІКІВ АПТЕЧНОГО ВИРОБНИЦТВА

з методичними рекомендаціями

для іноземних студентів спеціальності «226 Фармація, промислова фармація»

Англійською мовою