НФаУ

MANUFACTURING PHARMACEUTICAL PRACTICE IN PHARMACEUTICAL CHEMISTRY

METHODICAL RECOMMENDATIONS

MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department of medicinal chemistry
Department of pharmaceutical chemistry

MANUFACTURING PHARMACEUTICAL PRACTICE IN PHARMACEUTICAL CHEMISTRY

Methodical recommendations
for applicants for higher education

Kharkiv
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М 24

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М 24 **Manufacturing pharmaceutical practice in pharmaceutical chemistry :** Methodical recommendations for higher education applicants / V. Georgiyants, L. Perekhoda, L. Sydorenko et al. – Kharkiv : NUPh, 2023. – 20 p.

The methodological recommendations contain information on the purpose and objectives of pharmaceutical manufacturing practice in pharmaceutical chemistry, its content, procedure and summarizing. They will help higher education students during their practice and will help them prepare for the test.

They are intended for graduate students, as well as for supervisors at practice sites.

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CONTENTS

INTRODUCTION

Pharmaceutical manufacturing practice of applicants for higher education in pharmaceutical chemistry is one of the final stages of the process of training specialists in the specialty "Pharmacy, Industrial Pharmacy". The program of pharmaceutical manufacturing practice is compiled in accordance with the educational and professional program of training of pharmacy specialists and is aimed at the practical implementation of theoretical topics of the educational component in accordance with the requirements of the Law of Ukraine "On Higher Education" of 01.07.2014 № 1556-VII, Regulations on the practice of students of higher educational institutions of Ukraine (Order of the Ministry of Education of Ukraine of 08.04.1993 № 93), Instructions on the industrial practice of students of medical, medical, pediatric, medical and preventive, dental and pharmaceutical faculties.

In the context of the constant development of the pharmaceutical market and growing requirements for the quality of medicines, pharmaceutical chemistry, as a specialized educational component, should provide future specialists with both theoretical knowledge and practical skills in the field of quality control of medicines.

Pharmaceutical manufacturing practice in pharmaceutical chemistry is an important component of the educational process, which is based on theoretical knowledge and practical skills acquired at the university, transforming them into professional skills at the workplace: in pharmacies, quality control laboratories for medicines and medical devices, and central factory laboratories.

Thus, the correct organization of industrial practice ensures systematic, continuous and continuity of training.

According to the curriculum of the specialty "Pharmacy", pharmaceutical industrial practice in pharmaceutical chemistry is carried out in the following places:

10th semester (4.10d) – duration of practice is 3 weeks;

9th semester (4,6z) – duration of practice is 3 weeks;

8th semester (3.10d) – duration of practice is 3 weeks;

5th semester (2.6z) – duration of practice is 2 weeks;

The bases of industrial practice are pharmacies, pharmaceutical companies of various forms of management, laboratories for quality control of medicines and medical devices, central factory laboratories. The industrial practice is carried out according to the credit-module system in accordance with the requirements of the Bologna Process.

The program of pharmaceutical industrial practice in pharmaceutical chemistry consists **of one module.**

Control measures: semester differentiated credit.

During the practice, all activities of the higher education applicant are subject to control (carried out by the curators of the practice from the department and from the practice base).

PURPOSE AND OBJECTIVES OF PHARMACEUTICAL MANUFACTURING PRACTICE

Purpose and objectives: to consolidate and deepen the theoretical knowledge and practical skills acquired during the training and necessary for independent work in the performance of professional tasks of a pharmacist in the control and quality assurance of medicines.

Subject: control and quality assurance of medicines in the pharmaceutical industry.

Final goals of the practice. In order to form practical skills in the field of pharmacy, a higher education applicant must have the theoretical foundations of pharmaceutical analysis with their subsequent implementation in practical skills, including: organization of the State system of quality control of medicines of domestic and foreign production; organization of laboratories for quality control of medicines and medical devices; use of modern chemical, instrumental methods of analysis and pharmaceutical and technological tests; organization of the pharmacist's work place quality standards for medicinal products; certificates of quality of medicinal products; incoming control procedure; quality control of substances, industrial and pharmaceutical products; reporting documentation; possible directions of drug metabolism; familiarization with the storage conditions of medicinal products and prediction of possible changes in case of improper storage; ensuring rational pharmacotherapy of patients; interchangeability of medicinal products, etc.

Bases of practice pharmacies and hospitals approved in accordance with the established procedure and research laboratories of educational and research institutions that can ensure the implementation of the practice program may be used as practice sites in pharmaceutical chemistry. The organization of the process of industrial practice is carried out according to the credit-module system in accordance with the requirements of the Bologna process.

Contents. of industrial practice is covered in the following topics.

PHARMACEUTICAL MANUFACTURING PRACTICE PROGRAM
MODULE 1

Pharmaceutical manufacturing practice in pharmaceutical chemistry

Specific goals:

Analyze the structure of the organization of quality control of medicines in a pharmaceutical institution.

Interpret the provisions of the regulatory documents governing the quality control of medicines.

Master the procedure for incoming inspection of medicines.

Differentiate the features of pharmaceutical analysis of medicines depending on the place of practice: pharmacopoeia analysis, stage-by-stage control of drug production, analysis of industrial production, pharmacy manufacturing, express analysis.

Learn the procedure for keeping journals and reporting documentation.

Apply basic knowledge and skills to prepare titration, working solutions, indicators and reagents.

Identify substances and active ingredients in medicinal products (depending on the base of practice) using chemical, physical and physicochemical methods of analysis.

To make a preliminary assessment of the quality of the substance after determining the quality indicators given in the section of the monograph "Tests of Purity".

Make a preliminary assessment of the quality of medicinal products after conducting appropriate pharmaco-technological tests (disintegration of tablets and capsules, uniformity of weight per unit of dosed drug, uniformity of active substance content per unit of dosed drug, extractable volume, etc.)

Determine the quantitative content of substances by chemical and instrumental methods.

To master the types of control of medicines in a pharmacy in accordance with the current orders of the Ministry of Health of Ukraine and the State Fiscal Service of Ukraine.

Distinguish between the analysis of intra-pharmacy preparations: semi-finished products and concentrated solutions.

Interpret the results and draw a conclusion about the quality of the analyzed medicinal products.

Present the results of the quality control of medicines in the relevant documents.

Ensure rational pharmacotherapy based on knowledge of the chemical basis of action and interaction of drugs.

Study of drug interactions in order to identify possible incompatibility in terms of chemical, physicochemical and pharmacological properties with other drugs and food.

INDICATIVE STRUCTURE OF CREDIT - MODULE 1: PHARMACEUTICAL MANUFACTURING PRACTICE IN PHARMACEUTICAL CHEMISTRY

Topic	Practical work (hours)	SSS (hours)	Individual work
1. Organization of quality control of medicinal products and the workplace of a pharmacist-analyst; regulatory documents governing the quality of medicinal products: - Familiarization with the state system of ensuring quality control of medicines in Ukraine on the example of the place of practice; - familiarization with the workplace of a pharmacist-analyst, with his/her functional responsibilities; -familiarization with the functional responsibilities of the authorized person who carries out incoming control of medicinal products; - performing incoming inspection of medicinal products (raw materials, packaging materials, semi-finished products); - certification system for pharmaceuticals, quality assessment of pharmaceuticals prior to their entry into the market; – rules of storage of pharmaceuticals; – control over compliance with storage conditions and renewed	5/3	5/2	Work with educational and methodological, regulatory literature, lecture notes, and Internet resources.

Topic	Practical work (hours)	SSS (hours)	Individual work
expiration dates of medicinal products.			
2. Peculiarities of pharmaceutical analysis of medicinal products depending on the place of practice.	30/20	5/5	Work with educational and methodological literature, lecture notes, and Internet resources.
3. Quality control of finished medicinal products using chemical and physicochemical methods: - analysis of extemporaneous formulations and/or herbal raw materials and phytopreparations, ready made products (ready made dosage forms), depending on the place of practice; - purity testing as one of the quality parameters of medicinal products; -instrumental and chemical methods of analysis for quantitative determination of the active substance in medicinal products; - registration of the obtained results in accordance with the GMP.	20/11	20/13	Work with educational and methodological literature, lecture notes. Performing practical tasks.
4. Study of chemical and metabolic incompatibilities when prescribing several drugs, their analysis and recommendations on the rationality of joint use: - determination of the drug's belonging to a pharmacological group, taking into account the chemical structure; - Taking into account the physical, physicochemical and chemical properties of drugs, determine the features ofapplication and storage;	30/20	10/5	Work with scientific, educational and methodological literature. Conducting pharmaceutical care taking into account the pharmacological group and chemical structure, as well as metabolic features.

Topic	Practical work (hours)	SSS (hours)	Individual work
- ensuring rational pharmacotherapy based on knowledge of the chemical basis of action and interaction of drugs; - studying the interaction of medicines to identify possible incompatibility in terms of chemical, physicochemical and pharmacological properties with other drugs and food.			
5. Preparation of reporting documents based on the results of the practice.	4/4	5/5	Work with scientific, educational and methodological literature. Conducting pharmaceutical care taking into account the pharmacological group and chemical structure, as well as metabolic features.
Semester control of the module *«Pharmaceutical manufacturing practice in pharmaceutical chemistry»*	1/1	–	
Total hours – 135/ 90	***90/60***	***45/30***	
Credits ECTS – 4,5/ 3			

Audit work -66,67 %, SSS – 33,33 %

PLAN FOR PRACTICAL TRAINING OF HIGHER EDUCATION STUDENTS

1. To get acquainted with the organization of quality control of medicines in the pharmaceutical institution - the base of practice.
2. Get acquainted with the organization of the workplace of a pharmaceutical analyst, analyze his/her rights and responsibilities.
3. Develop legislative acts and regulations governing the quality control of medicinal products in a pharmaceutical institution.
4. Objects and features of quality control at a particular pharmaceutical enterprise.
5. Conduct incoming quality control of medicinal products during wholesale and retail sales. To learn the rights and obligations of the authorized person for quality control of medicines.
6. Determination of organoleptic quality indicators of pharmaceutical products.
7. Analytical part of the manufacturing regulations and the procedure for step-by-step quality control of medicinal products in accordance with the technological scheme of production.
8. Sampling and analysis of samples for analysis.
9. Quality control of outputs, intermediate products, raw materials and materials intended for the manufacture of finished products.
10. Quality control of medicinal products in accordance with the section of the technological regulations "Manufacturing control" and "Characterization of finished products".
11. Analysis of finished products according to the QMS.
12. The procedure for issuing a manufacturer's quality certificate.
13. Determination of transparency, turbidity, and color of liquids.
14. Determine the reaction of the solution medium, acidity, and alkalinity.
15. Determination of impurities in medicinal products.
16. Identification of active pharmaceutical ingredients by chemical, physical and physicochemical methods.
17. Determination of the quantitative content of active substances (in substances, pharmaceutical and industrial medicinal products, intra-pharmacy preparations) by chemical and physicochemical methods.
18. Master the methods of conducting pharmaceutical and technological tests in tablets, capsules, injectable solutions, eye drops, ointments, etc.
19. Quality control of pharmaceutical products manufactured in-house in accordance with the current legislation.

20. Express analysis of pharmaceutical products in a pharmacy.
21. Interpretation of the results of quality control of medicinal products.
22. Proper storage of medicinal products, medical devices and medicinal plant materials in a pharmaceutical institution.
23. Determination of the influence of factors that affect the processes of absorption, distribution, deposition, metabolism and excretion of the drug, as well as due to the state, characteristics of the human body and physicochemical properties of drugs. Determination of possible drug interactions in order to identify incompatibilities in terms of chemical, physicochemical and pharmacological properties with other drugs and food.

Recording the results of the practice in the relevant documentation:

1. Diary of manufacturing practice.
2. A written report on the work performed.

Review and characterization of the trainee applicant.

Diary – is the main and obligatory document for reporting on the practice by the higher education student. It reflects the daily work of the higher education student on the control and quality assurance of medicinal products (Appendix 1).

On the first day of the practice, the diary provides a brief description of the practice site and the pharmacist-analyst's workplace.

Within two weeks, the methods and results of the analysis of various medicinal products (depending on the specifics of the institution - practice base) - substances, medicinal products, concentrates, intra-pharmacy preparations - are presented. The daily diary entry should contain a full description of all necessary types of quality control of one or two medicinal products, their composition, a detailed description of the methods of analysis with the writing of chemical reaction equations, observations, a detailed description of calculations, and a conclusion on the compliance of the medicinal product with the requirements of the quality control evaluation.

In the last week of the practice, situations of pharmaceutical care with possible interchangeability of drugs are presented with theoretical justification of recommendations to patients for adequate replacement of drugs, taking into account the pharmacological group and chemical structure, as well as the characteristics of metabolism and interaction with other drugs and food in order to use them for rational pharmaceutical care of patients.

The higher education student is obliged to submit his/her diary to the immediate supervisor of the enterprise for verification and endorsement on a daily basis. The diary is kept until the end of the practice at the institution (enterprise) and must be available to the supervisor of the practice from the department.

After the end of the practice, the diary is certified by the signature of the head of the institution and the seal of the institution.

Report– a document written by a higher education student personally is not approved by the company's supervisor (Appendix 2).

The material for the report should be accumulated and summarized from the first day of practice. The report should give a general description of the institution, note the conditions and environment in which the higher education student worked, reflect the main content of the practice - the number of analyzes performed on certain types of work and list the methods of analysis used, conclusions about the implementation of the program. It is also necessary to show the difficulties that arose during the practice, positive and negative aspects in the organization of industrial practice, their participation in the social life of the company's team, as well as suggestions for improving the organization of industrial practice.

Review characteristics – is drawn up by the head of the practice site, signed by him/her and sealed by the institution. The review should assess both professional and personal qualities of the trainee (level of theoretical and practical training, attitude to work, etc.)

Upon arrival at the National University of Pharmacy, the trainee is obliged to submit the above documents to the department and pass the practice test to his/her supervisor from the department within the time limits established by the dean's office.

LIST OF QUESTIONS FOR SEMESTER CONTROL

MODULE 1

Pharmaceutical manufacturing practice in pharmaceutical chemistry

1. Structure and functions of the state system of quality assurance and control of medicinal products.
2. Legislative acts regulating the quality control of medicines in Ukraine.
3. Regulatory and technical documentation regulating the quality control of industrialized medicinal products.
4. Regulatory and technical documentation governing the quality control of pharmaceuticals manufactured by pharmacies.
5. European Pharmacopoeia, State Pharmacopoeia of Ukraine, its structure and content. Pharmacopoeial analysis.
6. Duties and rights of a pharmaceutical analyst.
7. Rights and obligations of the authorized person.
8. Incoming quality control of medicinal products during wholesale and retail trade and the procedure for drawing up documents for incoming control.
9. Pharmaceutical analysis and its importance for ensuring the quality of pharmaceutical products.
10. The main criteria for pharmaceutical analysis: specificity and sensitivity.
11. Determination of transparency, turbidity and color of drug solutions.
12. Testing of medicinal products for purity.
13. Use of physical, physicochemical and chemical methods of analysis in quality control of initial, intermediate products, raw materials, materials intended for the production of finished products.
14. Pharmaco-technological trials for the dosage form "Tablets", their significance and essence.
15. Pharmaco-technological trials for the dosage form "Capsules", their significance and essence.
16. Determination of mass homogeneity for a unit of dosed drug.
17. Determination of the uniformity of the content of the active substance in a unit of the dosed medicinal product.
18. Pharmaco-technological trials for the dosage form "Medicinal products for parenteral use", their significance and essence.
19. Definition of the "Extractable Volume" value.
20. Pharmaco-technological trials for the dosage form of "Eye medicinal products", their significance and essence.

21. Qualitative reactions to cations, anions, functional groups and their use for the identification of substances and active ingredients in medicines.
22. Physical methods of identification of substances.
23. Determination of the pH of the solution medium according to the requirements of the SPS.
24. Determination of the refractive index and its use to determine the purity and quantitative content of an active substance.
25. Polarimetry and its use for identification, purity testing and quantification of active substances.
26. Spectrophotometry and its use for identification, purity testing and quantification of active substances.
27. Classification of chromatography methods: thin-layer chromatography, liquid and gas chromatography, ion-exchange chromatography and others; their use in quality control of medicinal products.
28. The use of titrimetric methods of quantitative determination in pharmaceutical analysis.
29. The essence of gravimetry and its use in pharmaceutical analysis.
30. Types of internal pharmacy control of medicinal products in accordance with the requirements of the current order of the Ministry of Health of Ukraine.
31. Organoleptic control of dosage forms.
32. Physical control of dosage forms.
33. Chemical control of dosage forms.
34. Control of pharmacy-manufactured medicinal products during dispensing.
35. Basic requirements for qualitative and quantitative rapid analysis of dosage forms.
36. Analysis of medicinal products manufactured "for future use" in a pharmacy: concentrates, semi-finished products.
37. Requirements for the arrangement and operation of premises for storage of pharmaceutical products, peculiarities of storage of poisonous, narcotic and equivalent medicinal products, as well as dosage forms with them.
38. General requirements for the organization of storage of medicinal products and medical devices.
39. Peculiarities of storage of medicinal products taking into account their physical and chemical properties.
40. Peculiarities of storage of medicinal products and medical devices taking into account their terms of prescription.
41. Physicochemical properties of medicinal substances and their pharmacokinetics.

42. Influence of methods of drug administration on pharmacokinetic processes.
43. The main pathways of drug metabolism and factors affecting it.
44. Chemical incompatibilities. Chemical agonists, antagonists.
45. Storage of medical devices.
46. Measures to be taken in case of detection of expired medicinal products.

Measures taken to detect and prevent the distribution of counterfeit and substandard medicines.

FORMS OF CONTROL

The assessment of the student's performance in the educational component is a rating, is given on a stobal scale and is defined according to the ECTS system and the traditional scale adopted in Ukraine.

During the practice, all activities of the higher education student are subject to control (carried out by the curators of the practice from the department and from the practice base).

The semester control of the module is carried out upon completion of the practical implementation of the module in the form of a semester differentiated test, evaluated on a 100-point, four-point differentiated scale ("excellent", "good", "satisfactory", "unsatisfactory") and on the ECTS scale.

Types of assessment	**Maximum number of points (% of the number of points per module)**
Module "Industrial pharmaceutical practice in pharmaceutical chemistry"	
– ***evaluation of topics 1-5:*** – *oral survey,* – *test preparation.*	***100 (100%)***
Semester control	***100***

The total rating for the practice module does not exceed 100 points.

Evaluation of the educational component

Grades A, B, C, D, E are assigned only to higher education students who have passed a module from the educational component.

Rating scale

The sum of points on a 100-point scale	**Assessment. ECTS**	**Evaluation on a differentiated four-point scale**
90-100	A	excellent
82-89	B	good
74-81	C	
64-73	D	satisfactorily
60-63	E	
35-59	FX	unsatisfactorily
0-34	F	

The grade of the educational component FX, F is assigned to higher education students who have not been credited with the practice module after its completion.

The grade FX ("2") is assigned to higher education students who have scored the minimum number of points for current practical activities but have not passed the semester control of the module. They have the right to retake the semester control of the module no more than 2 times within 2 (additional) weeks after the end of the semester according to the schedule approved by the rector.

Higher education applicants who received a grade of F at the end of the practice (did not complete the module program or did not score the minimum number of points for the current manufacturing activity in the module) must undergo a repeated practice according to an individual plan.

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Appendix 1

Sample diary cover page

DIARY OF

Pharmaceutical manufacturing practice in pharmaceutical chemistry

higher education student(s) ____course_____ group NUPh

_____

(last name, first name)

Place of practical training _____

_____

_____

(name of the institution, enterprise, its address, telephone number)

Time of practice: from «_____» to «_____» 20__p.

Practice supervisor(s):

for the institution, enterprise _____

_____

(last name, first name)

from the department _____

(last name, first name)

Appendix 2

Report form

REPORT

on pharmaceutical manufacturing practice in pharmaceutical chemistry

higher education student(s) ____course _____ group NUPh

_____

(last name, first name)

Place of practical training _____

_____

(name of the institution)

Time of the practice: from«_____» to «_____» 20__p.

The contents of the report are as follows

Date. _____ **Signature of the applicant _____**

Навчально-методичне видання

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Федосов Андрій Ігоревич, **Абу Шарк** Амжад Ібрагім**,**
Гарна Наталія Василівна, **Бур'ян** Ганна Олександрівна,
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