PHARMACEUTICAL AND MEDICAL COMMODITY SCIENCE

methodical recommendations
for preparation to the final module control
MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY

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Methodological recommendations are developed in accordance with the work program «Pharmaceutical and medical commodity science» in specialty 8.12020101 – «Pharmacy» of educational program «Pharmacy» for the students of 4, 5 years. They contain theoretical questions, a list of recommended references, criteria for evaluating the knowledge, an example of a ticket to prepare of applicants for higher education for the final modular control on the discipline.

Methodological recommendations are intended to prepare for the final modular control of applicants for higher education specialty «Pharmacy» in discipline «Pharmaceutical and medical commodity science»
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INTRODUCTION

An important task of higher education in Ukraine is to ensure the quality of training specialists for the pharmaceutical sector at the level of modern international requirements. For this purpose, pedagogical methods of instruction are being improved, modern information technologies are being introduced into the educational process, a credit-module system of teaching and evaluation is being introduced, and the role of self-preparation and independent work on subjects of the discipline of persons seeking higher education is growing.

Training of qualified specialists in the pharmacy requires higher education applicants to in-depth study of the theory, develop and summarize the theoretical knowledge obtained in practical exercises, and obtain certain skills for independent research work.

Pharmaceutical and medical commodity science is the main discipline, the goal of which is the training of pharmacy specialists in the implementation of professional commodity functions related to the provision of medicines and medical products to the population and to medical and preventive institutions; teaching pharmacists practical skills in handling medical instruments, medical devices, equipment, etc.

The task of the discipline "Pharmaceutical and medical commodity science", which is an important link in the process of training applicants for higher education, is to provide theoretical knowledge for mastering the general concepts of commodity analysis of medicines and medical devices in accordance with the requirements of regulatory documentation; assimilation of the basic principles of the organization of quality control of pharmaceutical products when they are received and stored, familiarization with the current regulatory and legislative acts of Ukraine on the main aspects of quality control of medicines and medical devices in pharmacy chains and pharmacy stores in the pharmaceutical industry.

The goal of teaching the academic discipline "Pharmaceutical and medical commodity science" is the training of specialists for the pharmaceutical sector of the Health Care System of Ukraine, who have the necessary quantity of theoretical knowledge and practical skills to perform work related to the distribution of pharmacy products at all stages of the life cycle, means and products of medical purpose at the stages of transportation, storage and sale, falsified or substandard medicines at the entrance, check the conformity of the goods with the accompanying documents, compliance physical and chemical properties of pharmaceutical
packaging and marking requirements of the standard documentation, monitoring of compliance with the rules of transportation, and so on.

The practical orientation of the discipline is conditioned by the teaching of general provisions for the framework regulation of the quality of goods of the pharmacy assortment during transportation and storage, functioning of the modern pharmaceutical industry on the basis of information materials of modern domestic and foreign pharmaceutical productions.

The subject of studying the academic discipline "Pharmaceutical and medical commodity science" is the classification and assortment of goods, the scope of their application, the technical requirements for checking the quality parameters in the acceptance of goods, the rational choice of packaging, the requirements for container, closing and packaging, marking, organizing the storage and transportation of various types of goods.

Methodical recommendations on the final control prepared in accordance with the program of the credit module system, approved by the Ministry of Health of Ukraine for applicants for higher education in the specialty "Pharmacy".

At each lesson envisaged to study the range of medical products, ready-made medicines and goods that have the right to purchase and sell pharmacy institutions and their structural units, their classifications, quality assessments in accordance with the requirements of regulatory documents.

Methodical recommendations were compiled in accordance with the curriculum of academic discipline "Pharmaceutical and medical commodity science", educational training program and educational and qualification characteristics of the specialist in the specialty "Pharmacy" and contain theoretical questions and a list of recommended main sources of literature for the preparation of applicants for higher education to the final modular control, the criteria for assessing the knowledge, an example of a ticket.
LIST OF THEORETICAL QUESTIONS TO PREPARE OF APPLICANTS FOR HIGHER EDUCATION FOR THE FINAL MODULAR CONTROL

The MODULE 1. COMMODITY INSPECTION of MEDICAL PRODUCTS. PACKAGE, LABELLING, STORAGE.

Thematic module 1
THEORETICAL BASES OF COMMODITY SCIENCE. NORMATIVE DOCUMENTATION. CLASSIFICATION AND CODING OF GOODS. PACKING, MARKING OF MEDICAL GOODS

1. Concept about goods and their consumer value. Determining of concepts "goods", "range of the goods". Quality of goods as the basic grade of commodity study.
2. Occurrence and developing of commodity study.
3. The purpose and tasks of commodity study in system of pharmacist training at the present stage of developing of pharmacy. Integration of commodity study with other disciplines.
4. Determining of concept "standardization". Principles, levels, subjects and objects of standardization. The basic purposes and tasks of standardization.
7. Requirements to designatins of standards and standard specifications.
8. The order of statement and validity of normative documentation.
9. Packagings and purpose of medical equipment. Range and technical requirements.
11. Commodity inspection of medical equipment at its acceptance (conformity of a device to the accompanying documentation, completeness, integrity of package, conformity of labelling).
12. Concept about classifying of goods and its grades.
13. The purpose, assignment, characteristics and the general rules of classifying.
16. Bar coding.
17. Determining of concepts „inspection“, „commodity inspection“, „expert examination“, „commodity examination“. Functions, purposes and tasks of commodity inspection.
19. Requirements to medical and pharmaceutical goods. Main properties of materials (physical, chemical, technological, etc.), providing quality of goods.
20. Concept about commodity operations, their classifying and characteristics.
21. Acceptance and release of goods, quality estimation, organization of storage and transportation.
22. Process of turnover of goods in chemist's network and commodity operations connected with it. The order of composing of contracts with suppliers of medical and pharmaceutical goods.
23. Packagings, range of tools and equipment, used at work with plaster.
25. Classifying of equipment used in traumatology by its purpose, technical requirements to it.
27. Classifying of medical supplies depending on conditions of storage: by physical and chemical properties, ways of application, shelf-life, kinds and packaging methods. Organoleptic parameters of quality, requirements to quality of medical supplies.
30. Transport labelling. The basic, additional and information inscriptions. Handling instructions. The transport equipment. Technical requirements to transport containers.


32. Methods of disinfection and sterilization of parts of devices for survey, endoscopy and introscopy, contacting to patients.

33. Commodity inspection of devices for survey, endoscopy and introscopy at their accepting. Handle for devices and their storage.

34. Main factors influencing quality of pharmaceutical and medical goods. The general requirements to device and operation of storage premises.

35. The general requirements to organization of storage. Storage conditions of dressings and ready dressing means, rubber items.

36. Classifying of materials, their properties, use in pharmacy. Classifying, composition, properties, data on technology of their manufacture.

37. Requirements to quality. Labelling, package, conditions of storage. Sterilization.

38. Determining of concept "metals", their characteristic properties, classifying. The basic requirements to metal materials, medical items used for manufacture. Classifying of metals and alloys.


40. Nonferrous metals and their alloys (main range and definition). Physical and chemical properties of copper and its alloys. The basic copper alloys and their grades used for manufacture of medical tools.

41. Precious metals (range, properties and use in medicine). Concept about technological process of manufacture of medical goods.

42. Materials for manufacture of medical tools. Concept about corrosion of metals and protection against it.
44. Basic elements of design. Materials used for manufacture of medical tools.
47. Pushing aside tools (hooks, wound retractors, Bouyalsky spatula, spatulas, etc.). Classifying. Range. Technical requirements. Functional testing services.
50. The stomatologic equipment: stomatologic armchairs, drills, stomatologic apparatus, flexible sleeves, tips.
53. Classifying of special tools by purpose.
55. Ophthalmologic tools (scalpels and knives, scissors, eye spoons, loops, spatulas, tweezers, tools for pushing aside, probes, Filatov kit). Classifying, purpose, basic elements of design, range, technical requirements.
56. Otorhinolaryngologic tools. The diagnostic devices, cutting tools, tracheotomy tools, ear tools, auxiliary tools. Classifying, purpose, basic elements of design, range, technical requirements.
57. Urological tools. Catheters, bougies, probes, devices for crushing stones in bladder and their remove.
58. Classifying, purpose, basic elements of design, range, technical requirements.
60. Classifying, purpose, basic elements of design, range, technical requirements.
61. Classifying of nonmetallic materials, by their property, application in cosmetology, pharmacy and medicine.
63. Aging of rubber. Storage and recovery of rubber items.
64. Requirements to quality of rubber, labelling, package, storage, sterilization and disinfection.
65. Determining of concept "glass". Composition and properties of glass. Classifying of glass for medical items by purpose. Requirements to quality of materials, labelling, package, preserving, sterilization and disinfection.
66. Ceramic materials (determining, composition and properties). Requirements to quality of materials, labelling, package, storage, sterilization and disinfection.
68. General characteristic of natural and synthetic polymers and plastic on their basis (determining, composition). Classifying of plastics by use and composition. Data on technology of their manufacture.
69. Composition of plastics and requirements to their functional properties. Application of polymers in pharmacy and medicine. Requirements to quality of goods from plastic. Labelling, package, conditions of storage and sterilization of items from plastic.
70. Suture materials and their purpose. Classifying of suture materials.
71. Absorbable suture materials: catgut, oceslon, vicryl, etc. Non-resolving suture materials: linen strings, strings of lavsan, horse hair, wire metal, Michel's brackets.
73. Package, labelling, transportation and storage of suture materials in conformity to standards.
74. Surgical needles. Classifying of needles by use: surgical, skin, of general purpose (thick and thin), eye, cutting away, intestinal (bent, direct, with flat-oblong part), vascular (bent and straight), kidney. Packagings.
75. Classifying of needles depending by their design: by shape, degree of bend, section and edge, by eye shape, size.
78. Syringes for injections. Classifying of syringes by design and purpose. Syringes of "Record" type (folding, combined, of continuous action). Syringes for washing cavities and injections (Jean type). Glass syringes of "Luer" type, polymeric ones. Syringe - tube.
80. Trocar. The equipment for transfusion, forcing and aspiration.

**MODULE 2. COMMODITY INSPECTION of MEDICAL PRODUCTS.**
**PACKAGE, LABELLING, STORAGE**

**Thematic module 3**
**GOODS THAT HAVE THE RIGHT TO PURCHASE AND SELL PHARMACY ESTABLISHMENTS AND THEIR STRUCTURAL SUBDIVISIONS. CONTAINERS FOR PHARMACEUTICAL APPLICATION**

81. Concepts about disinfection, sterilization and pre-sterilization processing. Methods of disinfection and sterilization in medicine and pharmacy.
82. Physical methods of disinfection and sterilization (thermal sterilization, IR-, VHF, UV–sterilization, radiation and plasma sterilization) of medical and pharmaceutical goods.
84. Equipment for sterilization (steam sterilizer, dry heat sterilizer, gas sterilizer, sterilization boxes, etc.).
85. Classification of steam sterilizers: by design, method of heating, handling. Stationary, portable, s.
86. Equipment for radiation sterilization of medical instruments, suture materials and drugs using electron beams and gamma-rays. Plasma sterilizers.

87. Equipment for disinfection (portable boilers, stationary boilers, disinfection chambers, shower disinfection units, hydraulic sprayers, «Dezinfal'» nebulizers, nebulizers.
89. Storage of medical leeches and care for them.
92. Chemical reagents and their classification. Reagents in pharmacy and control-analytical service. Assortment of chemical reagents. Requirements for their quality. Packaging, labelling, transporting and storage of chemical reagents.
94. Release of oxygen to s from apothecary shop. Disinfection processing of oxygen pillows and tips after their use. Rules of safety during work with oxygen. Account of the released oxygen.


98. Assortment of consumer containers. Glass, metal and polymeric container and technical requirements to them. Cardboard containers and technical requirements to them.


100. Storage of containers. Organization of container facilities. Organization of container (multiturn container, certificate for returned containers, penalties, report about of containers.

101. Classification of closures by their use, features, method of fixing, materials, methods of production.

102. General, special and sanitary-hygienic requirements to closures. Storage.

103. Package materials and requirements to them. Classification, assortment. Storage of package materials.

104. Commodity kinds, assortment of devices and apparatus for diagnostics. Classification of diagnostic devices by purpose.

105. Methods of disinfection and sterilization for parts of diagnostic apparatus contacting with patients.

106. Commodity expert analysis of diagnostic devices at their acceptance. Care for devices and their storage.

**Thematic module 4**

**PACKAGE, MARKING, TRANSPORTATION OF MEDICAL PRODUCTS. ORGANIZATION OF STORAGE OF MEDICAL PRODUCTS AND ITEMS OF MEDICAL PURPOSE. ACCEPTANCE OF GOODS IN PHARMACEUTICAL WAREHOUSE**

107. Classification of drugs depending on storage conditions, by pharmacological action, physical and chemical properties, methods of application, terms of shelf-life, method of
production, aggregate state, kinds and methods of packing, organoleptic indexes of quality, requirements to quality of dosage forms.


111. Acceptance of commodities pharmacy warehouse by and quality. Release of commodities from pharmacy warehouse.

112. Basic factors influencing quality of pharmaceutical commodities.

113. Requirements to drugs and their storage. Requirements to storage of different groups of drugs depending on their physical and chemical properties.

114. Control of quality, stability and shelf-life of drugs.


117. Apothecary glassware. Facilities of mechanization used in pharmacy shops.


119. Furniture for laboratories and pharmacy shops, their technical descriptions. Tables, cases, trucks. Commodity kinds. Requirements to them.

120. Instruments and devices for laboratory researches. Devices for weighting and determination of .

121. Apparatus for heating and thermostatting.

122. Apparatus for distillation. Equipment for centrifugation and filtration.
CRITERIA OF ASSESSMENT THE KNOWLEDGE OF APPLICANTS FOR HIGHER EDUCATION

The final modular control (FMC) is carried out after the completion of the study of module 1 (discipline) in the last lesson.

For the final module control allowed only those applicants for higher education, who performed all kinds of work, provided in the work program and took a minimum of 36 points for the current activity (for the study of module 1), and a maximum of 60 points (the sum of the thematic module = TM 1 + TM 2).

The total sum of FMC is a maximum of 40 points and minimum 25 points.

Means of checking level of preparation by applicants for higher education:

- theoretical survey (oral or written)
- decision practical tasks

Structure of ticket by applicants for higher education:

- 3 theoretical questions are estimated to be between 0 and 10 points (3 theoretical question × 10 = 30 points) (see table);
- 2 practical tasks are estimated to be between 0 and 5 points (2 tasks × 5 = 10 points) (see table);

When developing criteria for evaluating as the basis are taken completeness and correctness of tasks. As well as takes into account the ability by applicants for higher education to differentiate, integrate and unify knowledge.

ASSESSMENT OF THEORETICAL KNOWLEDGE

One theoretical questions of FMC are estimated to be between 0 to 10 points.

<table>
<thead>
<tr>
<th>Rating mark (points)</th>
<th>Criteria of assessment</th>
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<tbody>
<tr>
<td>9-10</td>
<td>Gets the applicants for higher education who, when answering the question, found a comprehensive, systematic, in-depth knowledge of program material, can correctly interpret the results; demonstrate knowledge of basic and additional literature, provided for at the level of creative use.</td>
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</tbody>
</table>
6-8 Gets the applicants for higher education who, when answering the question, showed full knowledge of the program material provided at the level of similar reproduce, but made some minor mistakes.

3-5 Gets this points if, in answering a question, the applicants for higher education showed insufficient knowledge of the basic program material that is necessary for further education and work provided by the program at the level of reproductive reproduction.

0-2 Gets this points if, in answering a question, the applicants for higher education identified the serious gaps in knowledge basic material and made principle mistakes.

**ASSESSMENT OF PRACTICAL SKILLS**

One practical tasks of FMC are estimated to be between 0 to 5 points.

<table>
<thead>
<tr>
<th>Rating mark (points)</th>
<th>Criteria of assessment</th>
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<tr>
<td>5</td>
<td>If the practical (situational) task is fulfilled by the applicants for higher education independently and without mistakes. He also knows how to correctly justify the presented results, skillfully uses terminology on the basis in-depth knowledge of program material.</td>
</tr>
<tr>
<td>4</td>
<td>the practical (situational) task is fulfilled by the applicants for higher education without mistakes, substantiated the results, demonstrated knowledge of program material, provided at the level of similar reproduce, but made some minor mistakes.</td>
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<tr>
<td>3</td>
<td>The practical task is fulfilled, however the applicants for higher education does not know how to correctly interpret the results.</td>
</tr>
<tr>
<td>0-2</td>
<td>The applicants for higher education could not fulfill the practical task.</td>
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## SCALE FOR ASSESSMENT: NATIONAL AND ECTS

<table>
<thead>
<tr>
<th>The sum of points for all types of educational activity</th>
<th>ECTS scale</th>
<th>National scale</th>
<th>For the final marks</th>
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<tbody>
<tr>
<td>90 – 100</td>
<td>A</td>
<td>“EXCELLENT”</td>
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</tr>
<tr>
<td>82-89</td>
<td>B</td>
<td>“GOOD”</td>
<td>Pass</td>
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<tr>
<td>74-81</td>
<td>C</td>
<td></td>
<td></td>
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<tr>
<td>64-73</td>
<td>D</td>
<td>“SATISFACTORY”</td>
<td></td>
</tr>
<tr>
<td>60-63</td>
<td>E</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-59</td>
<td>FX</td>
<td>“UNSATISFACTORY but with the possibility of a second re-examination”</td>
<td>Not pass but with the possibility of a second re-examination</td>
</tr>
<tr>
<td>0-34</td>
<td>F</td>
<td>“UNSATISFACTORY with a mandatory re-study of the discipline”</td>
<td>Not pass with a mandatory re-study of the discipline</td>
</tr>
</tbody>
</table>
EXAMPLE OF TICKET

MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY

Educational background ____________________________ Specialist ____________________________
(Lack of Educational Background)
program subject area ____________________________
1202 - Pharmacy __________________________________
(Program Subject Area Title and Code)
Specialty__ 8.12020101 - Pharmacy __________________ Semester ________ 10 ____________
(Specialty Title and Code)
Educational program ____________________________ Pharmacy ____________________________
(Educational Program Title)
Course unit ____________________________ Pharmaceutical and medical commodity science
(Course Unit Name)

FINAL MODULAR CONTROL
MODULE NO. 2 «TITLE»

EXAMINATION PAPER No. 2

THEORETICAL

1. Specify goods, which chemist’ shops and their structural units have right of selling and buying.
2. Write about stock control card
3. Give the following definitions «Desinfective means» and «Glass bottle»

PRACTICAL

Task 1. List the requirements for the premises and equipment of the area

Requirements for premises and equipment of storage area

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Size</th>
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Task 2. Name the designation of the Ukrainian registration number of the finished medicinal product

<table>
<thead>
<tr>
<th>№</th>
<th>UA/1005/03/01 (Lamisil 1%, cream)</th>
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<tbody>
<tr>
<td>UA</td>
<td>1005</td>
</tr>
<tr>
<td>03</td>
<td>01</td>
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</table>

Approved at the Department Meeting

<table>
<thead>
<tr>
<th>Commodity science</th>
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</table>

Examination Record No. 1 from 28.08.2017

Department Chairman, Prof. Baranova I. I.

Examiner,

(QueNano) (Signature)

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LIST OF MAIN REFERENCES FOR PREPARATION TO THE FINAL MODULAR CONTROL


Навчальне видання

Баранова Інна Іванівна
Безпала Юлія Олександрівна
Халавка Марина Василівна
Коваленко Світлана Миколаївна

ФАРМАЦЕВТИЧНЕ ТА МЕДИЧНЕ ТОВАРОЗНАВСТВО

методичні рекомендації
з підготовки до підсумкового модульного контролю

Національний фармацевтичний університет.
61002, Харків, вул. Пушкінська, 53
Свідоцтво серії ДК № 3420 від 11.03.2009.