Topic: INSPECTION and EXPERT EXAMINATION of PHARMACEUTICAL and MEDICAL PRODUCTS

The objective: To acquire knowledge concerning concepts of inspection and expert examination of pharmaceutical and medical goods. To study functions, purposes, tasks, peculiarities and main stages of commodity inspection. To get professional knowledge and skills while inspecting various groups of goods.

Basic concepts and terms which should be acquired by students during their training and studying

Inspection of goods, an expert, commodity examination, technological examination, economic examination, ecological examination, sanitation examination, authorized person, properties of materials used for manufacture of products for medical care, consumer properties of goods.

Questions for self-training

1. Give the definitions for terms «inspection of goods», «expert examination of goods».
2. In what cases inspection and expert examination of goods are needed?
3. What main kinds of expert examination can be distinguished depending on their purposes and professional occupation?
4. When is commodity examination carried out?
5. In what cases technological examination is needed?
6. Reasons when sanitation examination is necessary.
7. Reasons for ecological examination.
8. In what cases economic examination is necessary?
9. Define functions, purposes and tasks of commodity inspection.
10. Define peculiarities of inspection of pharmaceutical and medical goods.
11. Stages of commodity inspection.
12. In what cases laboratory researches of goods are needed?
13. What requirements are showed to materials for medical use?
14. What kinds of reference documentation (RD) regulate requirements to materials for medical use?
15. What basic parameters of materials provide consumer properties of goods for medical use? Main methods of their evaluation.
16. An authorized person and his duties.

Methodical maintenance of the class

1. Order of the Ministry of Health of Ukraine №436 from 30.10.2001 "About assertion of the Instruction about order for quality control of drug products during their wholesale and retail trade".
2. ДКПП 016-97. State Ukrainian Classifier of Products and Services.
3. Items of medical goods for inspecting.
4. RD for the medical goods to be inspected.
5. Drug products.
6. Analytical reference documentation or/and Pharmacopoeia.

Task N 1

Into drug warehouse ready drug products (RDP) was delivered. Carry out inspection of the RDP offered by the teacher and make a conclusion about possibility of their further turnover.

Write down results of the inspection in the table 1.

Working technique

Step 1. Check up accompanying documents for RDP arrived: invoice, waybill, tax waybill, quality certificate. Example of accompanying document is given in annex 4.2.

Step 2. Check up conformity of all parameters of RDP, specified in accompanying documents and actually arrived into warehouse: the name of payee and sender, their registration status, name of manufacturer, batch number, quantity of goods, name of RDP, requirements of the ARD and results of the analysis according to the quality certificate of the manufacturer, presence of stamps, presence of signatures.

Step 3. Carry out organoleptic (mainly visual) control of:

- secondary (outer) package: presence or absence of such defects as: pollution, dents, tears, attritions, stains, swelling as a result of moisture absorption, runs of typographic paints; accuracy of labeling and color design;
- primary (immediate) package: integrity of containers, closures, sealing, first opening control.

Step 4. Check up marking of RDP according to Orders of MoH:

- on secondary package: country of the manufacturer, name of enterprise – manufacturer, its trade mark and address, name of RDP in national (e.g., English, Russian, Ukrainian) and Latin language, drug formulation, quantity of RDP, its concentration, activity or doze, composition and quantity of active substance(s), way of administration, batch number, expiry date, registration number, storage conditions, bar code;
- on primary (immediate) package:
    - on ampoules, syringe-tubes, dropper-tubes: name of RDP, its concentration or activity, quantity of a drug (in gr. or ml), batch

number, expiry date;

- on blister package and tubes: name of RDP, its concentration or activity, quantity of a drug (in gr. or ml), batch number, expiry date, name of the proprietor of registration certificate;

Step 5. Check up barcode of RDP:

- scan barcode and determine country of origin and manufacturer of the goods;
- if scanning fails, check up test digit of a barcode.

Step 6. Check up completeness of RDP: presence or absence of leaflet (instruction for use), dosing devices, and other devices if needed.

Step 7. Carry out organoleptic inspection of contents in RDP package according to requirements of ARD and/or Pharmacopoeia:

7.1. Tablets: they are usually right, circular solid cylinders, surfaces of which are flat or convex and edges of which may be bevelled. They may have lines or break-marks and may bear a symbol or other markings. Tablets should have proper form, their edges should be unbroken, without crumbled places, be hard enough, and surface should be smooth and homogeneous. Tablets with toxic substances should have special colouring.

7.2. Dragee should have proper spherical form; surface should be uniform and smooth, homogeneous in colouring.

7.3. Granules should be homogeneous in colouring and size.

7.4. Capsules should have proper form, should be transparent or painted, have no bubbles and inclusions, dents and mechanical pollutions. Surface of capsules may bear markings.

7.5. Powders should be flowable, homogeneous across the entire mass.

7.6. Tinctures, extracts, syrups should be transparent, without any stratification or deposit (if otherwise is not indicated in the ARD or Pharmacopoeian monograph), have taste and smell, characteristic for initial raw material.

7.7. Eye drops should not contain any visible mechanical impurity. Eye drops in form of solutions should be transparent, and suspensions can form deposit easily redispersable after agitation, forming stable suspension.

7.8. Solutions for injections should not contain any mechanical impurities even those non-visible with naked eye. Colouring of a solution should correspond to the color standard specified in RD.

7.9. Ointments, liniments, creams and pastes should be homogeneous and plastic.

7.10. Gels should be homogeneous, transparent and free from mechanical inclusions.

7.11. Rectal and vaginal dosage forms (suppositories, globules, rods, etc.) should be homogeneous, have proper form and sufficient hardness.

7.12. Plasters should be homogeneous, sticky layer should provide sufficient adhesion.

Step 8. Basing on the results of inspection of accompanying documents,

secondary and immediate package and its content, make a conclusion about possibility of RDP acceptance.

Table 1.

Results of the inspection analysis of RDP _____
(name of the good)

Name of parameter	Characteristics	
	According to the requirements of RD	Those of the goods researched
Organoleptic (visual) control of packing		
Marking of the goods		
Definition of the country-manufacturer by a barcode		
Testing of check digit of a bar code		
Completeness of the goods		
Organoleptic analysis of the goods		

The conclusion: _____

Task N 2

Carry out inspection of the dressings offered by the teacher and make a conclusion about possibility of their further turnover.

Write down results of the inspection in the table 2.

Working technique

Steps 1–3 are the same as for task 1 (see above).

Step 4. Check up marking of dressing package according to RD (GOST 1172-93, 1179-93, 16427-93, etc.): Red Cross emblem, country of the manufacturer, name of enterprise – manufacturer, its trade mark and address, name of the dressing in national language, size or weight, designation of the RD, sterility, manufacturing or sterilization (for sterile dressings) date, expiry date, registration number, storage conditions, bar code.

Step 5 is the same as for task 1 (see above).

Step 6. Check up completeness of dressing package according to RD (GOST 1172-93, 1179-93, 16427-93, etc.). E.g., first-aid packs are checked for presence of bandage (movable and fixed bolsters, gauze bandage), clasp-pin, internal and external

rubberized fabric shell.

Step 7. Carry out organoleptic inspection of dressing package according to corresponding RD. E.g., according to GOST 9412-93 medical gauze should have the following characteristics (see table 4.1 of Annex 4):

reaction of its aqueous extract is neutral;

wettability – not more than 10 sec. (for cotton one) and 60 sec. (for mixed one);

capillarity – not less than 10 cm/hr;

moisture content - 5,0-8,5 %.

Holes in gauze sheet more than 5 cm in size; oily and dirty spots; strapped edges of a fabric more than 1 m long are not allowed.

Loose picks of more than three threads, edge fringes more than 1,5 cm on one side and more than 2 cm on another side are not allowed.

Step 8. Basing on the results of inspection of accompanying documents and dressing packages make a conclusion about possibility of their acceptance.

Table 2.

Results of the inspection analysis of dressings _____
(name of the goods)

Name of parameter	Characteristics	
	According to the requirements of RD	Those of the goods researched
Organoleptic (visual) control of packing		
Marking of the goods		
Definition of the country-manufacturer by a barcode		
Testing of check digit of a bar code		
Completeness of the goods		
Organoleptic analysis of the goods		

The conclusion: _____

Task N 3

Carry out inspection of the rubber products offered by the teacher and make a conclusion about possibility of their further turnover.

Write down results of the inspection in the table 3.

Working technique

Steps 1–3 are the same as for task 1 (see above).

Step 4. Check up marking of rubber products according to RD (GOST 2667-94, 2909-94, 3302-05, 3-88, etc.):

- on package of the goods: country of the manufacturer, its name, trade mark and address, name of rubber products, their type, their quantity, batch number, date of manufacture, warranty shelf-life, registration number, storage conditions, barcode, designation of the RD;

- immediately on an item (for some groups of rubber products): e.g., marking of rubber hot-water bottles should contain trade mark of the manufacturer, name of a product, its type, capacity, designation of the RD, date of manufacture, quality control stamp.

Step 5 is the same as for task 1 (see above).

Step 6. Check up completeness of rubber products according to RD (GOST 2667-94, 2909-94, 3302-05, 3-88, etc.). E.g., rubber hot-water bottles of B-type are checked for presence of a bottle with mounted liner, plug, rubber tape, screwed closure with orifice, tips (for children, for adults, uterine cannula), rubber tube, valve, instructions for use, label.

Step 7. Carry out organoleptic inspection of rubber products according to corresponding RD: presence or absence of defects – cracks, foreign inclusions, agnails, color heterogeneity, manifestation of rubber aging, etc.

Step 8. Basing on the results of inspection of rubber products, make a conclusion about possibility of their acceptance.

Table 3.

Results of the inspection analysis of rubber products _____
(name of the goods)

Name of parameter	Characteristics	
	According to the requirements of RD	Those of the goods researched
Organoleptic (visual) control of packing		
Marking of the goods		
Definition of the country-manufacturer by a barcode		

Testing of check digit of a bar code		
Completeness of the goods		
Organoleptic analysis of the goods		

The conclusion: _____

Task N 4

Carry out inspection of the medical instruments offered by the teacher and make a conclusion about possibility of their further turnover.

Write down results of the inspection in the table 4.

Working technique

Steps 1–3 are the same as for task 1 (see above).

Step 4. Check up marking on package of medical instruments according to RD (GOST 19126-79, 21238-77, 21239-77. 21240-77, etc.):

On retail container or on label attached thereto the following information should be specified (see example 4.3 in Annex 4):

- trade mark or name of the enterprise - manufacturer;
- graphical symbol and (or) name of the instrument if symbol is absent;
- number of the instrument in case of package by separate numbers;
- conventional sign "H" or "Stainless steel" (for instruments of corrosion-resistant steel), "Ti" or "Titan" (for instruments of titanic alloys);
- designating of the standard or standard specifications used in manufacturing of the instrument;
- stamp of quality control department;
- number of instruments in one package;
- date of manufacture.

Marking put immediately onto non-working part should include:

- number of the instrument or its designating (in case of manufacture by several numbers);
- trade mark of the enterprise - manufacturer;
- year of manufacture (two last digits);
- conventional signs "H" (for instruments of stainless steel), "Ti" (for instruments of titanic alloys).

It’s allowed to print abovementioned marking onto retail containers or labels attached to instruments if it’s impossible to mark a tool with 2 mm font or a tool is to be in contact with a human body more than 6 hours or marking of a tool can change its functional properties.

Step 5 is the same as for task 1 (see above).

Step 6. Check up completeness of medical instruments according to RD (GOST 19126-79, 21238-77, 21239-77. 21240-77,etc.): instruments should be provided with accessories, disposable or/and spare parts, specified in corresponding RD.

Step 7. Carry out organoleptic inspection of medical instruments: presence of rustproof oil on items, presence or absence of defects – cracks, foreign inclusions, agnails, non-uniformity of covering, rust, presence and arrangement of components, etc.

Step 8. Basing on the results of inspection of medical instruments, make a conclusion about possibility of their acceptance.

Table 4.

Results of the inspection analysis of medical instruments _____
(name of the goods)

Name of parameter	Characteristics	
	According to the requirements of RD	Those of the goods researched
Organoleptic (visual) control of packing		
Marking of the goods		
Definition of the country-manufacturer by a barcode		
Testing of check digit of a barcode		
Completeness of the goods		
Organoleptic analysis of the goods		

The conclusion: _____

Name of the product	Purpose	Marking according to RD	Package according to RD	Technical requirements according to RD	Conclusion
Medical gauze	For manufacture of dressings	➢ trade mark of the enterprise - manufacturer; ➢ name of the item and article number; ➢ total length of gauze in a pack, stack or roll; ➢ total length of conditional cuts; ➢ designation of the RD; ➢ manufacturing date; ➢ batch number	Packs of the bleached gauze are wrapped up with paper and tied with a twine, then completed into bales 80 kg in weight and then packed into a fabric or a nonwoven cloth according to the GOST 5530. Rolls of the bleached gauze are wrapped up with paper and packing fabric.	1. By physical and chemical properties bleached gauze should conform to requirements of the standard: ➢ reaction of its aqueous extract should be neutral; ➢ wettability should be not more than 10 sec. (for cotton one) and 60 sec. (for mixed one); ➢ capillarity – not less than 10 cm/hr; ➢ moisture content - 5,0-8,5 %. 2. Holes on a background of gauze more than 5 cm in size; oily and dirty spots; strapped edges of a fabric more than 1 m long are not allowed. 3. Loose picks of more than three threads, edge	Conform (Does not conform) to requirements of the GOST 9412-93.

				fringes more than 1,5 cm on one side and more than 2 cm on another side are not allowed.	

The sender: *Company «Drug warehouse»* **License** *АБ №109006 from 02.03.2005*
The receiver: *Drugstore №5*
Bank requisitions: *acc. №0003549170 in the bank "Privatbank", МФО 025386*
The contract № *31*

№	Code	Name of products	Batch N	Unit of accounting	Quantity	Manufacturer price	The margin, %	Wholesale price without VAT	The sum without VAT	The margin, %	Retail price	In total
1.	*0134*	*Analginum tabl. 0,5 № 10*	*150108*	*pack*	*10*	*0,50*	*10*	*0,55*	*5,50*	*10*	*0,60*	*6,00*
2.	*0215*	*Asparcam tabl. 0,5 № 50*	*250507*	*pack*	*10*	*2,00*	*10*	*2,20*	*22,00*	*10*	*2,42*	*24,20*
3.	*0543*	*ATP 1 % in 1 ml amp. № 10*	*831207*	*pack*	*10*	*2,00*	*10*	*2,20*	*22,00*	*10*	*2,42*	*24,20*

Quantity of items ***3***

In total without VAT **goods** *54,40 (fifty four grivnas and 40 copecks)*
containers- 0,00
VAT - 0,00
Total *54,40 (fifty four grivnas and 40 copecks)*
Payment during *5* **days**
-
The goods are sent by / _____ / *Ivanov A.A*
The goods are accepted by _____ /*PetrovO.O./*
The goods are received **on** *"10" February 2008.*

Quantity of transport places **1**
Places accepted **1** **signature:**_____

The name	Code of the goods	Characteristics of package	Appearance of the goods	Conformity to requirements of RD – GOST 19126-79			The conclusion (e.g.)
				Technical requirements	Marking (according to RD)	Storage	
Scalpel, pointed, medium		Retail container – cardboard box (GOST 12301-2006). Group container – cardboard pack (GOST 12303-80). Shipping container – returnable wooden box (GOST 9396-88). In case of low quantity of instruments it is allowed to put different kinds of them into the same shipping container. Surfaces of consumer (retail) and group containers have no skews, cracks, tears, deformations, apertures, folds.	The instrument consist of the handle, neck and blade.	The instrument is made of corrosion-resistant material – stainless steel 40X13. On surface of the item there are no cracks, blisters, nicks, crumbled places, agnails, stratifications.	Marking <u>put onto non-working part of a tool</u> includes: - number of the instrument or its designating (in case of manufacture by several numbers); - trade mark of the enterprise - manufacturer; - year of manufacture (two last digits); - conventional signs "H" (for instruments of stainless steel), «Ti» (for instruments of titanic alloys). <u>On retail container or on label attached</u> the following information should be specified: – trade mark and/or name of the enterprise - manufacturer; – graphical symbol and (or) name of the instrument if a symbol is absent; – number of the instrument in case of package by separate numbers; – conventional sign "H" or "Stainless steel" (for instruments of corrosion-resistant steel), "Ti" or "Titan" (for instruments of titanic alloys); – designation of the standard or specifications used in manufacturing of the instrument; – stamp of quality control department; – quantity of instruments in one package; – date of manufacture.	Surgical instruments and other metal goods should be stored in heated well ventilated premises at relative humidity of air not higher than 65 %. Medical instruments are stored by types and names inside cases or on racks in original manufacture package or in other additional containers (boxes, paper or polyethylene packs). Each package is supplied with label indicating instruments stored therein.	The instrument itself conforms to the requirements of RD. Labeling doesn't conforms to the requirements of RD – there is no trademark of the manufacturer on the instrument.