**EXAMPLE OF TICKET FOR EXAM**

**Kazan State Medical University**

**of Ministry of Health of the Russian Federation**

**Institute of Pharmacy**

**Exam on Medical and Pharmaceutical Commodity Science**

**Examination ticket 2**

**1. Coding of medical and pharmaceutical products. Barcode – classification, structure and methods of decoding barcodes. *(20 points)***

**2. Otorhinolaryngological instruments: cutting and tracheotomy instruments. Appointment, types, quality control (tests), material for production. Conduct a commodity analysis of a medical instrument “Adenotome”. *(50 points)***

**3. Hormonal medicines: medicines of sex hormones. Hormonal contraceptives. Assortment, trade names. Dosage forms. Application. Packaging, labeling, storage. *(30 points)***

**1st question.**

**Coding** – a formation and assignment of a code to a classification grouping and / or object of classification.  
  
**Code** - a sign or a set of signs used to name a classification grouping and / or object of classification.

The *purpose of coding* is to systematize objects by identifying them, ranking them and assigning a symbol (code) by which any object can be found and recognized among many others.

Coding is carried out based on the *following rules:*  
· The code must have a certain construction structure;  
· The code can be expressed using various, predetermined characters;  
· The code should contribute to the order of objects.

A **barcode** is a machine-readable symbol that contains encoded information about the characteristics of a manufactured product and allows its automated identification.

Each item of products is identified by a barcode and digital code. For example, the digital 13-bit product code 4902580420222 includes:  
  
49 – country code  
02580 – manufacturer code  
42022 – product code  
2 – check digit (control number)

**Barcode classification:**

UPC (Uniform Product Code) is a universal product code used primarily in America (it is called American).

EAN (European Article Numbering) - the European Article Numbering code, is used most often in European countries (called European). EAN-codes can be 8, 13 and 14-numbered (13-numbered is the most used one).

The first two or three digits of the EAN-13 barcode indicate the code of the country where the organization registered the manufacturing factory, its products and assigned their serial numbers. The next five or four digits indicate the manufacturing company code. The manufacturer's code is assigned centrally by the appropriate national authority in the country for the specific manufacturer. The last digit of the EAN-13 code is the control one, which is designed to check the correctness of the barcode reading by the scanner. The check is performed automatically using the EAN algorithm or manually.

**Decoding barcode**

1. Add all the numbers in the barcode in even places and multiply this number by 3.

2. Add up all odd-numbered digits except for the last digit (checksum).

3. Next, you need to add the results and discard the tens, i.e. leave the last digit of the amount received.

4. Subtract the result from 10 and compare it with the check digit (control number). If the values match, everything is in order, otherwise the barcode is fake, or the checksum is calculated incorrectly. Also other different reasons are possible (for example, registration holder is one country and the company which produced this product is located at another country).

**2nd question.**

***Cutting ENT instruments.***

They are used for surgical interventions in otorhinolaryngology. They have peculiar shapes, determined by the fact that they have to be introduced into tight cavities and passages, without losing visual control over their working part.

**a) The** **crescent ear scalpel** is intended for deep incisions over a short distance, for example, abscesses in the ear canal. It is made of steel 40Cr13 or U12A, the handle is made of stainless steel 12Cr18Ni9Ti. The sharpness test is carried out by cutting the glove leather with a thickness of 0.7-0.9 mm, stretched over the drum.

**b)** **Polypous loops** are used to remove polyps formed as a result of a chronic inflammatory process of the mucous membrane of the nose, throat, and ear. They are produced in three types, differing in the size and degree of bending of the tube: *laryngeal (a), nasal (b) and ear (c).*

**c)** **Adenomatomas (adenotomes)** are used to cut off adenoid growths in the nasopharynx. The adenotome has a ring-shaped knife made of solid steel, connected by a long rod with a faceted handle. The blade along the entire length of the cutting edge must be sharp and bent. Functional tests are carried out by cutting a thin layer from the painted surface of the chrome leather. The adenotome must easily, without sawing movements, make a clean cut. Five numbers are produced depending on the width of the knife (width 18, 19, 20, 21 and 22 mm).

**d)** **Tonsillotomas** are used to cut hypertrophied palatine tonsils. The instrument has two moving ring knives and needles that fix the cut tissue, which allows cutting the tonsils at their base. Produced in three numbers, differing mainly in the size of the knife. Tests of functional properties are performed by cutting thin suede, introduced in the form of a rope with a diameter of 3-4 mm into a ring knife. The cut on the suede must be smooth and clean.

**e)** **The laryngeal knife** is used to open the pharyngeal abscesses. The instrument resembles a throat loop, it is a hidden sharp knife; the end of which, when the manipulation rings come together, protrudes from the tube and cuts the tissue. Cutting tests are carried out on a suede drum.

**f)** **The paracentesis knife-needle** (F) serves for puncture and dissection of the eardrum, carried out in case of acute inflammation of the middle ear. The blade is in the form of a spear with a sharpness angle of 33 °. Manufactured from U8A-U12A carbon instrumental steel. Cutting tests are carried out on a drum by piercing the capacitor paper, piercing must be without clicking.

**g) Conchotome** serves to cut dense neoplasms and growths of the nasal conchas observed in chronic hypertrophic rhinitis and other diseases. It is the forceps with ring (oval) holes in jaws or with jaws in the form of spoons. Conchotomes are made of stainless steel in two sizes. The cutting properties are tested by cutting thin suede (up to 1.0 mm) or by biting off a celluloid plate 0.3 mm thick; the edges of the cut must be straight and smooth.

**h) Gouges for otorhinolaryngology** are intended for grinding bone tissue during operations in the ear and nose. The following types of gouges are produced: flat - blade width 4 and 6 mm, grooved - blade width 2, 4, 6 and 8 mm, grooved curved - blade width 3.5 and 4 mm and angular. Length 150 mm, ribbed handle. Made of 40Cr13 stainless steel. Gouges must be sharp (cutting edge width 60 - 80 mm). Long gouges (190 mm) with a square handle are also produced.

**i) Raspatory for otorhinolaryngology** are designed to separate and cut dense tissues. For micro-operations on the ear, miniature raspatory are used: straight with a blade width of 0.6 mm and curved with a width of 1.5 mm.

***Tracheotomy instruments.***

**a) Tracheotomy tube** is used for tracheotomy (throat section) for the passage of air into the respiratory tract with stenosis of the larynx. In view of the developing suffocation an incision is made below the constriction, and a tube is inserted into the trachea, through which air enters the lungs, bypassing the narrowed larynx. The tube is removed after elimination of the symptoms of stenosis, which usually happens after a few days. If, as a result of trauma, subsequent necrosis or performed surgery scars are formed and persistent narrowing remains, then wearing a tracheotomy tube is prescribed for a long time.

The tracheotomy tube is arranged in the following way. A second tube is inserted into a short curved tube fixed to a shield, which is fixed in it with a lock. The inner tube must freely enter the outer one. The gap between the walls of the tubes in the collected state must not exceed 0.2 mm, and the difference in length is allowed no more than 0.5 mm. The edges of the tubes must be blunt. The tube is secured around the neck with a gauze bandage attached to the holes in the shield.

The tube is made of silver or a corrosion-resistant metal alloy - galvanized nickel silver. The surface of the tube must be flat, smooth and clean.

**b) Trachea dilators** are designed to dilute the edges of the incision in the trachea when a tracheotomy tube is inserted into it. They are produced in several standard sizes: with short working jaws; a Wolfson dilator with extended working jaws and a dilator with a cremaliera (ratchet), which is automatically held in the desired position. Dilators are made of stainless steel 30Cr13.

**c) A sharp tracheotomy hook** is designed to hold the trachea during tracheotomy. To do this, a sharp hook is inserted into the cricoid cartilage and, with slight pulling up by the larynx, 2-3 tracheal cartilages are dissected. They are produced in two types: for adults and children. Made of steel 30Cr13.

**d) Pneumointubators** are used in cases of acute stenosis of the larynx in its upper section, which occurs in diphtheria. With the help of a tube inserted into the larynx between the vocal cords (intubation), the lumen of the larynx expands and allows air to flow freely into the lungs. The set of pneumointubator, which replaced the previously produced "Intubation Set", includes: an intubator and a set of six tubes, and a tip for connecting the tube with an oxygen cushion. The set is produced in a polystyrene box.

***Commodity analysis of and instrument “Adenotome”.***

1. Name of the instrument – adenotome.

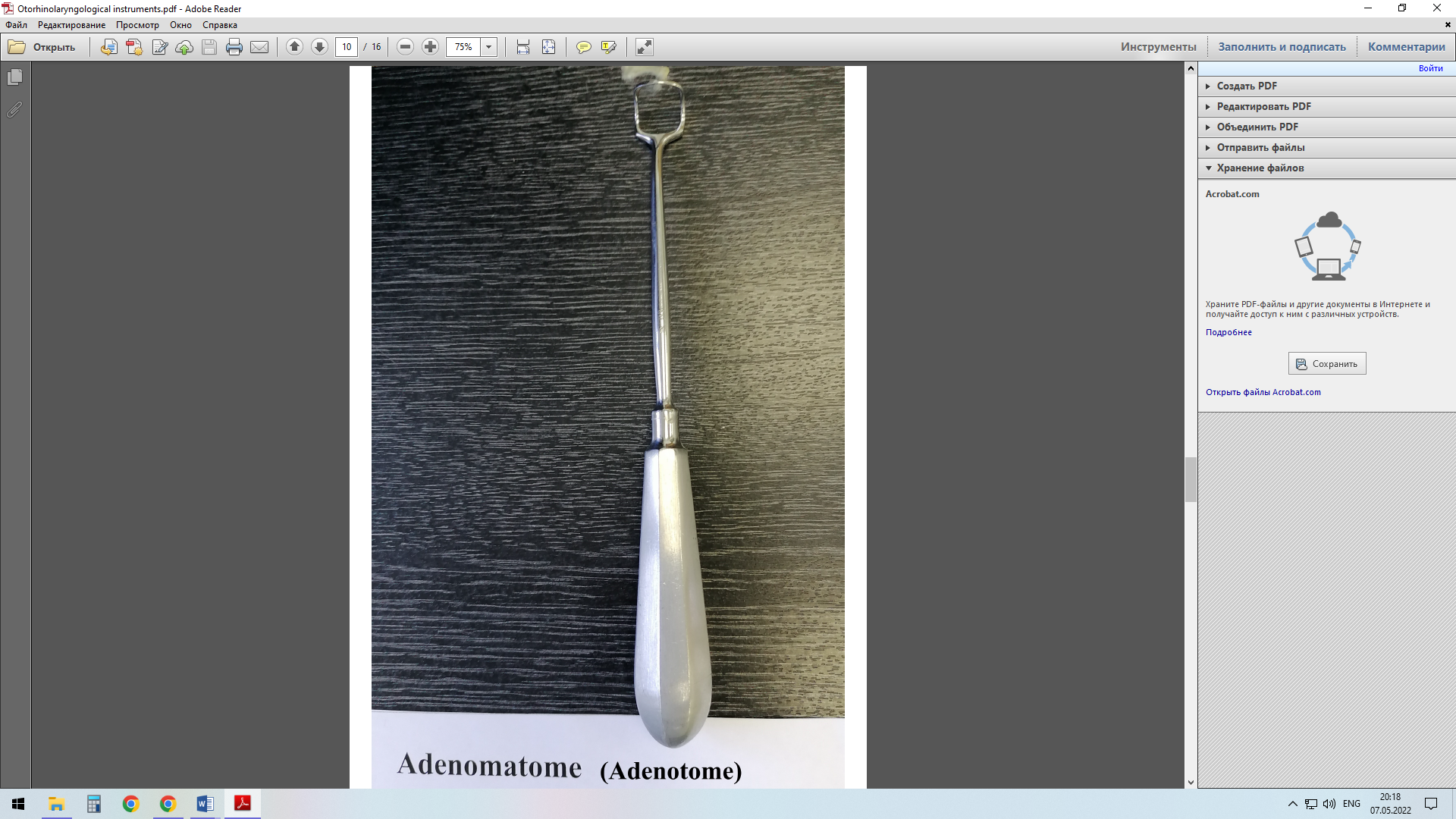
2. Classification group – othorhinolaryngological instruments.

3. Purpose. Is used to cut off adenoid growths in the nasopharynx.

4. Other types. Five numbers are produced depending on the width of the knife (width 18, 19, 20, 21 and 22 mm). From other cutting ENT instruments: tonsillotome, polypous loop, crescent ear scalpel, laryngeal knife, etc. can be distinguished.

5. Material, from which it is made. Made from stainless steel.

6. Schematic drawing with indication of its parts. Consists of a ribbed handle, a neck and a working part – a sharp knife.



7.1. Organoleptic characteristics – check for cracks, dents, corrosion, etc.

The instrument is in a good condition, but small corrosion dots can be seen in the working part.

7.2. Test for working properties.

Functional tests are carried out by cutting a thin layer from the painted surface of the chrome leather. The adenotome must easily, without sawing movements, make a clean cut.

8. Packaging of the instrument.

Instruments made of stainless steel should be preserved using one of the methods recommended by the normative documents, wrapped in waxed or inhibitor paper and packed in a cardboard box, 5 pieces each. In our case, the instrument was not packaged.

9. Labeling (marking) of the instrument and packaging.

Due to the fact that there is no packaging, there is no labeling on the packaging.

10. Storage of the instrument.

When storing the adenotome, a free, stress-free condition should be provided. The following requirements are imposed on the storage conditions of metal medical instruments in the warehouse: air temperature is about 20 ºC, humidity is not more than 60%, sudden changes in temperature and humidity are not allowed. All instruments should be greased with preservative oil, wrapped in waxed paper and packed in cardboard boxes of 5 pieces.

11. Sterilization of the instrument.

Sterilization of metal medical instruments is carried out by dry heat at a temperature of 180 ºC for 60 minutes in dry ovens.

Output (conclusion).

As a result of the commodity analysis, it was found that the accepted instrument is an adenotome, made of stainless steel. The quality of the adenotome (appearance, functional properties) meets the requirements of regulatory documents, but there is no packaging, the instrument is not greased or wrapped in paper. Also it has a little corrosion. The instrument can be left for storage and can be used in the future only after a complete quality check has been carried out in accordance with the normative documents, appropriate conservation and packaging.

**3rd question.**

**Medicines of sex hormones.**

***Classification.***

1) Medicines of female sex hormones - estrogens, antiestrogens, progestogens, hormonal contraceptives.

2) Medicines of male sex hormones - androgens, antiandrogens, anabolic steroids.

*Estrogens* are used for:

- lag in sexual development,

- some forms of endocrine infertility,

- the period of menopause,

- climacteric disorders in women,

- violations of the menstrual cycle,

- dysfunctional uterine bleeding,

- oral contraception;

- prostate cancer in men.

Estradiol (INN) (Divigel, Oestrogel) – produced in the form of transdermal gel, transdermal therapeutic system (plaster), tablets.

Estriol (INN) (Blissel, Ovestin) – produced in tablets, vaginal suppositories, vaginal cream and gel.

Ethinylestradiol (INN) (Microfollin – Hungary) – available in tablets.

***Antiestrogens*** are used for:

- estrogen deprivation therapy in the treatment of positive breast cancer;

- ovulation induction in infertility due to anovulation;

- for male hypogonadism;

- for gynecomastia (breast development in men).

Tamoxifen (INN) (the same trade name, Zitazonium) – produced in the form of tablets.

Exemestane (INN) (the same trade name, Aromasin) – produced in tablets.

Clomifen (INN) (the same trade name, Clostilbegyt) – produced in tablets.

***Progestogens*** are used for:

- threatened miscarriage in early pregnancy (up to 16 weeks),

- menstrual irregularities,

- dysfunctional uterine bleeding,

- he treatment of estrogen-dependent breast cancer,

- prostate cancer,

- some types of infertility,

- contraception,

- abortions for medical reasons in the first trimester.

Progesterone (INN) (Prajisan, Progestogel, Utrogestan) – produced in capsules, gel, vaginal gel, oil solution for injections.

Dydrogesterone (INN) (Duphaston) – available in tablets.

Norethisterone (INN) (Norcolut) - available in tablets.

**Hormonal contraceptives.**

***a) Combined oral contraceptive pills (COCP)*** - a group of hormonal contraceptives to prevent unwanted pregnancy, containing two types of hormones - estrogens and progestins.

Combined oral contraceptives can be of three types: monophasic - containing 21 tablets with the same amount of estrogen and progestogen; diphasic - containing 21 tablets with two different combinations of estrogen and progestogen; triphasic - containung 21 tablets with three different combinations of estrogen and progestogen.

Examples of monophasic oral contraceptive pills:

Microgynon (trade name – Germany) – tablets containing levonorgestrel and ethinylestradiol.

Logest (trade name – Germany) – tablets containing gestodene and ethinylestradiol.

Femoden (trade name - Germany) – tablets, containing gestodene and ethinylestradiol.

Cilest (trade name – Russia/Switzerland) – tablets, containing norgestimate and ethinylestradiol.

Lindynette 20 and 30 (trade name – Hungary) – tablets, containing gestodene and ethinylestradiol.

Novynette (trade name – Hungary) – tablets, containing desogestrel and ethinylestradiol.

Examples of diphasic oral contraceptive pills:

Angiovin (trade name – Hungary) – 11 tablets and 10 tablets with different amount of levonorgestrel and ethinylestradiol.

Examples of triphasic oral contraceptive pills:

Tri-Merci (trade name – Ireland/Spain) – tablets of 3 types, containing desogestrel and ethinylestradiol (of yellow color, of red color, of white color by 7 pieces each).

Tri-Regol (trade name – Hungary) - tablets of 3 types, containing levonorgestrel and ethinylestradiol (of pink color in 6 pieces, of white color in 5 pieces, of dark yellow color in 10 pieces).

***b) Progestogen-only pills or progestin-only pills (POP)*** are contraceptive pills that contain only synthetic progestogens (progestins) and do not contain estrogen. They are colloquially known as mini pills.

Microlut (trade name – Germany; Levonorgestrel – INN) – available in dragee.

Exluton (trade name – The Netherlands, Lynestrenol – INN) – available in tablets.

Cerazette (trade name – The Netherlands, Desogestrel – INN) – available in tablets.

***c) Emergency contraception*** applied in taking medications specially designed for this, within the prescribed period (no later than 72 hours after unprotected intercourse), or installing an intrauterine device no later than 120 hours after unprotected intercourse. According to WHO recommendations, emergency contraception should not be a regular method of contraception.

Postinor, Escapelle (trade names – Hungary; Levonorgestrel – INN) – available in tablets of 2 pieces for Postinor and 1 piece for Escapelle.

***d) Injectable contraceptives.***

This is a method of hormonal contraception, which includes the introduction of hormonal contraceptives by injection. Women are given intramuscular injections of progestin every 3 months. Among women, it is very much inferior to oral contraceptives, since the injection of progestin, like any other injection, is very painful. Hormonal contraceptives can be absorbed in the intestines with the same success, while this procedure is completely painless, unlike hormonal injections. Therefore, women prefer oral contraceptives to hormonal injections, but hormonal injections usually have one plus: one injection is enough to maintain the contraceptive effect for several months.

Depo-Provera (trade name – USA/Belgium, Medroxyprogesterone – INN) is used in the form of suspension for injections.

***e) Other types of hormonal contraceptives.***

NuvaRing (trade name – The Netherlands; Ethinylestradiol+Etonogestrel -INN) represent a hormonal contraceptive vaginal ring.

Mirena (trade name – Germany/Finland; Levonorgestrel – INN) is an intrauterine device, which represent a small device made of plastic with copper.

Evra (trade name – Russia/Germany/Belgium; Ethinylestradiol+Norelgestromin - INN) - transdermal therapeutic system (plaster).

Implanon (trade name – The Netherlands; Etonogestrel – INN) is used as subcutaneous implant, as well as in combined hormonal contraceptives in the form of a vaginal ring.

**Medicines of male sex hormones.**

***Androgens:***

Testosterone (INN) (Androgel, Nebido) - is used for insufficiency of sexual function in men, as well as in menopause in women, also in oncology. Produced in capsules, injection solution and gel for external use.

Methyltestosterone (INN) (the same trade name mainly) is used to normalize the growth and development of the male reproductive system and in oncology of the mammary glands. Available in tablets.

***Antiandrogens:***

Finasteride (INN) (the same trade name, Proscar, Finast, Finpros) is used for benign prostatic hyperplasia. Available in tablets of 5 mg.

Cyproterone (INN) (the same trade name, Androcur, Bellune 35) is used for pathologically increased sexual activity in men, with symptoms of masculinization and acne in women, with early puberty in children. Available in tablets and oil solution for injections.

Flutamide (INN) (the same trade name, Andraxan) is used for in prostate cancer.

***Anabolic steroids:***

Nandrolone (INN) (Retabolil, Nandrodec, the same trade name in some countries) - belongs to the group of male sex hormones, has a long-term anabolic activity (3-4 weeks). It is used for various asthenic conditions, cachexia, for violations of protein anabolism after major operations, diseases, also in female oncology.