Lecture 8

features of pharmacy manufacturing of medicines

organization of intra-apical quality control of medicines

pharmacy manufacturing of medicines

the main document of this topic is Order of the Ministry of Public Health of the Russian Federation No. 751n

Order of the Ministry of Public Health of the Russian Federation No. 751n of October 26, 2015 on the endorsement of the rules of manufacture and release of medicines for medical application by apothecary organisations, individual entrepreneurs having a license for pharmacy activities

the pharmacy produces medicines according to individual prescriptions of doctors some pharmacies make medicines according to doctors' prescriptions and requirements of medical organizations

This is individual production for each patient separately

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the manufacture of medicines in a pharmacy is carried out by a pharmacist .-

the pharmacist is responsible for the work –

the pharmacist's work is controlled by a senior pharmacist, pharmacist technologist, production manager, pharmacist analyst, dispensing chemist. any of them.

after making the medicine the pharmacist fills out the passport of written control.

the pharmacist signs the prescription

upon which pharmacist transmits medicine and prescription to the pharmacist technologist for control.

a pharmacist has no right to produce several medicines at the same time.

special attention must be paid in the manufacture of medicines containing potent substances and substances to be accounted for.

the pharmacist technologist weighs this substances and issues them to the pharmacist according to the recipe.

after receiving these substances the pharmacist uses them immediately for the manufacture of medicine.

the main room for manufacturing of medicines in a pharmacy is an assistant room.

the assistant communicates with the prescription, office of the pharmacist analyst, material room and washing room.

for the manufacture of injectable and infusion drugs, ophthalmic medicines and medicines for newborn children special aseptic conditions are required
complex of premises for manufacturing under aseptic conditions it is called an aseptic block the aseptic unit consists of pre-aseptic, sterilization, aseptic room

it is placed separately from sources of air contamination by microorganisms ..

2.Organization of the manufacture of medicines according to doctors' prescriptions and requirements of medical organizations

pharmacy activities for the manufacture of drugs we can be characterized as follows

-the prescriptions are diverse in composition –
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- they are diverse in dosage forms
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- the prescriptions are complex in composition –
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the pharmacy-made medicines have a short shelf life

at the same workplace the pharmacist makes several types of medications of varying complexity in various dosage forms. this is a necessity

- manufacturing requires high costs
- manufacturing has a low profitability for pharmacy

- medicinal substances for the manufacture of medicines in a pharmacy must be registered as medicinal substances

- the pharmacy must have a pharmaceutical activity license with the right to manufacture of medicines and manufacturing of medicines under aseptic conditions
manufacture of medicines in a pharmacy is carried out according to the rules of pharmacy production
the rules are approved by the order of the Ministry

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a pharmacist makes medicines in a pharmacy in the special assistant room
the general view of the assistant room is shown in the picture

room dimensions and equipment depends on the number of recipes.
In the assistant room are placed:
- assistant tables for the manufacture of medicines;
-table and floor bookcases - turntables for medicinal substances;

- safes and metal cabinets for storage of toxic substances, narcotic drugs, ethyl alcohol

- measuring devices of the weight and of the volume

substances for the manufacture of medicines, concentrated solutions of medicinal substances are in special glass shtanglasses or ceramic containers

reagents for chemical quality control of water and medicines
are placed on the table of the pharmacist analyst

The organization of the manufacture of medicines in pharmacies is carried out in three directions.

1st direction. Auxiliary works are being carried out: preparation of water, air, detergents and disinfectants, premises, equipment, packaging and closures, auxiliary materials, sanitation. specialist. clothes. As well as the staff itself.
2nd direction. The actual manufacture of medicines, in which separate stages and operations can be distinguished.
For example: production of a powder mixture, its dosing, packaging of dosed powders in group containers, labeling
3rd direction elimination of marriage, equipment cleaning is carried out by pharmacy staff.

the pharmacy produces:
- medicines according to individual prescriptions (prescriptions and requirements of medical organizations)
- concentrate solutions (used to reduce the time spent in the manufacture of medicines)
- semi-finished products (intermediate intermediates
to accelerate the manufacture of medicines)
- intra-apical packaging (packaging of factory-made medicines, in smaller packages by weight or volume)
- intra-apical preparation (production of a series of more than 10 units according to frequently occurring prescriptions of pharmacy-made medicines)

quality control of pharmacy medicines

The quality of each drug manufactured in a pharmacy must be checked before being released to the patient.
This control is called intrapharmacy.
The pharmacy uses 5 types of intra-pharmacy control:
- physical,
- chemical (high-quality and complete)
- organoleptic
- questionnaire
- written. -

Each type of control is used by the pharmacist-analyst on a mandatory or selective basis.

Mandatory are written and organoleptic control.

For purified water, injections and infusions, drugs for newborns, concentrates and semi-finished products, chemical control is mandatory.

In other cases, physical, chemical and polling types of control are selective.

Physical control.

This type of control is carried out by checking the mass or volume of the medicinal product. For example: weight of powder, weight of ointment, volume of solution, volume of medicine

Chemical control.

This type of control is divided into qualitative and complete. Qualitative chemical control consists in checking the presence or absence of substances in a drug solution or powder. For example, checking the quality of purified water should confirm the absence of chloride ions, sulfate ions, reducing substances, pyrogenic substances.

Full chemical control shows the presence of substances and their quantitative content. It is used to control solutions for injections, solutions for infusions, medicines for newborns, solutions of concentrates and pharmaceutical preparations. For example, sodium chloride solution 0.9%, glucose solution 5%, novocaine solution 2%.

Organoleptic control is selective. Sight and smell are used. Visually, you can evaluate the homogeneity of the ointment, the fineness of the powder, the absence of sediment or mechanical inclusions in solutions.

Poll control is selective. A pharmacist technologist or a pharmacist analyst can check how the pharmacist prepared the medicine. After manufacturing, he calls the pharmacist the first component of the prescription, then the pharmacist must name the remaining components of this medicine.

survey control –опросный контроль
опрос — interrogation, quiz, debriefing, perquisition
Poll control, question control, control by conversation

Written control is mandatory for all drugs manufactured in a pharmacy, as well as pharmacy solutions of concentrates and semi-finished products. The pharmacist must fill out a written control passport indicating the substances taken and their quantity, put the date and his signature.

The pharmacist-analyst records all the results of the control in the drug quality control logs. Each analysis is given a number and date. These data are indicated on the label of each medicine. The pharmacist analyst is responsible for this work.

To perform quality control of medicines in a pharmacy, a table or an analyst's office is necessarily organized. The pharmacy has devices and reagents for quality control of medicines.

Terms

Laboratory work in a pharmacy is understood as those works in which technological techniques are used: weighing, measuring, mixing, rubbing, filtration, etc.
As a result of these works, intermediate products are obtained, which are later used in the manufacture of ready-to-release LP, the retail price for it is not formed.

Filling works in pharmacies are understood as those works in which a single technological technique is used: division into doses by measuring or weighing.
As a result of these works, products that have a free retail price are ready for sale to the final consumer.

Laboratory packaging works in pharmacies are understood as those works in which various technological techniques are used: weighing, measuring, mixing, rubbing, filtration and separation into doses by measuring or weighing.
As a result of these works, products that have a free retail price are ready for sale to the final consumer.

Concentrated solutions (concentrates)- these are pre-prepared solutions of medicinal substances of a higher concentration than the concentration in which these substances are prescribed in prescriptions.

Semi-finished products are an undosed type of preparation used in a mixture with other ingredients, which is an integral part of a complex dosage form (LF).

Intra-apical preparation (VAZ) is the preliminary production of LP according to frequently occurring prescription prescriptions.

Intra-apical packaging - dosing of drugs in quantities suitable for sale to customers – a medicinal product (LP).
For one LP manufactured in a pharmacy in the order of intra-apical preparation and packaging, a single package is accepted in a ready-to-release form, issued in accordance with the established rules.
Design of labels for packaging.
Packaged medicines are issued with labels of the established sample, on which the following should be indicated:
- pharmacy number, its details: name, logo, if any, legal address);
- full name of the packaging products, its dosage (in Russian);

- date of manufacture;
- serial number of manufacture;
- analysis number;
- price.
- shelf life
- home storage conditions (you can use separate warning labels).

Marking and registration for vacation.

All medicines manufactured in pharmacy organizations are labeled and issued for release According to these rules, the following main labels of signal colors are provided for the registration of extemporal dosage forms and VASES:
■ "External" — orange;
■ "Internal" — green;
■ "For injection" — blue;
■ "Eye drops", "Eye ointment" — pink.
Warning labels are printed on all labels:
"Store in a cool and protected from light place" (for eye dosage forms, ointments and medicines),
"Shake before use" (for medicines),
"Store in a place protected from light" (for drops of internal use),
"Keep away from children" (all dosage forms)
On the labels of medicines containing narcotic drugs or psychotropic substances manufactured according to doctors' prescriptions, the stamp "Poison" is applied in black ink
The following details must be present on all labels used for the registration of manufactured medicines:
1. Emblem (bowl with snake),
2. location and name of the pharmacy organization
3. recipe number,
4. medicinal prescription – for vases and packaging
5. general method of application (external, internal, for injection, etc.),
6. date of manufacture, series, analysis number
7. retail price
On the labels of medicines made according to individual prescriptions, instead of a medicinal prescription, the name of the patient and the detailed method of use indicated by the doctor in the prescription are indicated.
All designations in the text of labels are printed in Russian or national languages.