National university of Pharmacy
Technology of drugs department

Discipline “Pharmacy-based technology of drugs”

The topic of the lecture :

SOLUTIONS FOR INJECTIONS

a lecture for English students of 3rd course
in the speciality “Pharmacy” for foreign students

Lecturer: associate professor Yuryeva A.B.

Plan of the lecture

1. Characteristics of medicinal forms for injections.
2. Stages of technological process of preparing solutions for injections.
3. Filtration.
4. Packing.
5. Registration for dispensing.

QUESTIONS FOR SELF-STUDY

1. Filtering of solutions
2. Control of the absence of mechanical impurities

REFERENCES:

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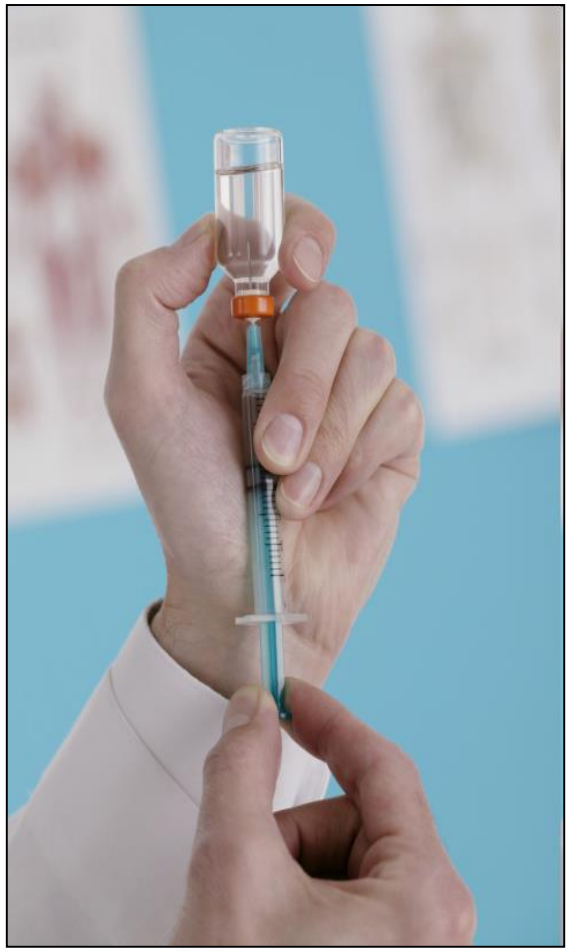
1. Tikhonov A.I., Yarnykh T.G., Yuryeva A.B., Garkavtseva O.A. Chemist's Technology of Drugs: The manual for students of higher schools / Ed. by A.I. Tikhonov and T.G. Yarnykh. – Kharkiv: NUPh; Original, 2011. – 424 p
2. Tikhonov A.I., Yarnykh T.G., Yuryeva A.B., Gaydukova Ye.A., Oleynik S.V., Kovalyova O.A. Sterile medicines and medicines requiring aseptical conditions of preparation. lectures for English students in the speciality "Pharmacy"/ edited by acad. A.I. Tikhonov. – Kh.: NUPh, 2010. – 164 p.
3. Dry, liquid and soft medicinal forms. A textbook for English students in speciality "Pharmacy" / A.I. Tikhonov, T.G. Yarnykh, A.B. Yuryeva, L.N. Podorozhna, S.S. Zuykina; Ed. by A.I. Tikhonov. – Kharkiv: NUPh; Original, 2011. – 208 p.
4. Tikhonov A.I., Yarnykh T.G., Yuryeva A.B., Podorozhna L.N., Zuykina S.S. Biopharmaceutics. Lectures for English students on the speciality "Pharmacy": a handbook for the out-of-class work of students/ edited by acad. A.I. Tikhonov. – Kharkiv: NUPh, Original, 2011. – 140 p.

1. CHARACTERISTICS OF MEDICINAL FORMS FOR INJECTIONS

Less. 21, q.1



- Medicinal forms for injections include:
  - sterile aqueous solutions;
  - non-aqueous solutions;
  - suspensions;
  - emulsions;
  - dry solid substances (powders, tablets, etc.) which are dissolved in sterile solvent before use.

Types of injections (depending on the place of introduction): intracutaneous, subcutaneous, intramuscular, intravenous, intra-arterial, spinal, intracranial, etc.

1. CHARACTERISTICS OF MEDICINAL FORMS FOR INJECTIONS

Less. 21, q.1

Solutions for injections

Hypotonic solutions

Causes hemolysis (breaking of membranes of erythrocytes).

Hypotonic solutions are prepared only if it is indicated in the prescription by a doctor (in rare cases).

Isotonic solutions

Solutions, which osmotic pressure equals osmotic pressure of the body liquids (blood, plasma, lymph), i.e. 7.4 atm.

Hypertonic solutions

Causes plasmolysis (loss of shape of erythrocytes)

Hypertonic solutions are prepared only if the exclamation mark in a prescription is present.

1. CHARACTERISTICS OF MEDICINAL FORMS FOR INJECTIONS

Requirements to solutions for injections:

✓absence of particulate matters;
✓sterility;
✓stability;
✓apyrogenicity;
✓isotonicity (to some solutions).

Less. 21, q.1

Advantages

- fullness of absorption
- escape of protective barriers of organism
- no need of taste and odour correction
- exact dosage of medicinal substances, etc.

Disadvantages

- possibility of damage in the place of injection;
- need of the medical staff;
- possibility of infection, etc.

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

Prescription

↓

Check of correctness of:
drawing up of prescription, prescribing and compatibility of ingredients, doses, norms of delivery of medicinal substances

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Preparatory stage

↓

Calculations of medicinal and auxiliary substances quantities → Written control

↓

Sanitary preparation of staff, room and equipment

↓

Preparation of solvents, medicinal and auxiliary substances, packaging materials

↓

Control of sterility
(room, substances, working place)

↓

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

Technology of solutions for injections:

Preparation in measuring flask

- Weighing out dry substances (active, isotonizing agents)
- Measuring water for injections (half of measuring flask volume)
- Measuring stabilizer solutions
- Add water for injections until the mark
- Mixing

Preparation in auxiliary glass bottle

- Measuring calculated volume of water for injections
- Weighing out dry substances (active, isotonizing agents)
- Measuring stabilizer solutions
- Mixing

<u>Chemical control</u>

(qualitative and quantitative)

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

Corking with rubber corks

⇓

Filtering

<u>Control of particles absence</u>
(on white and black background)

⇓

Corking by aluminum cover

<u>Control of hermetically sealing</u>

⇓

Sterilization

<u>Sterilization control</u>
(time, temperature, preasure)

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

Control of particles absence

Polling control

Secondary quality control

Physical control

Chemical control

Preparation of labels and signatures

Registration for dispensing

Control of the finished product

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

Less. 21, q.2

NB!

I. Preparatory work.
II. Preparation of solution.
III. Chemical and physical quality control of solution (primary control).
IV. Filtration.
V. Control for particles absence.
VI. Packing of solution
VII. Packing control.
VIII. Sterilization of solution.
IX. Sterilization control (temperature, time, pressure (for autoclaving))
X. Secondary quality control (control for particles absence).
XI. Registration for dispensing.

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

General rules of preparing solutions for injections:

It is forbidden to prepare solutions for injections when the methods of their complete chemical analysis, sterilization mode, data of the chemical compatibility of the ingredients and formulation are absent.

The simultaneous preparation of several solutions for injections which include different ingredients or the same ingredients, but in the different concentrations, is forbidden.

Preparation of solutions for injections is performed by the weight and volume method where the medicinal substance is taken by weight, and solvent is taken until the definite volume of the solution is obtained.

2. STAGES OF TECHNOLOGICAL PROCESS OF PREPARING SOLUTIONS FOR INJECTIONS

General rules of preparing solutions for injections:

Dissolution of medicinal substances is carried out in sterile volumetric flasks. When the glassware for measuring is absent, the required amount of the solvent is determined by calculation using the density value of the solution with the given concentration or the volume increase coefficient.

In large inter-hospital and hospital chemist's shops dissolution of medicinal substances is carried out in glass 20 liter reactors equipped by electric heating. The process of the liquid's mixing is mechanized with the help of mixers of different types.

3. FILTRATION

Types of filters

The main way of filtration of solutions for injections. The principle of its working is creating rarefaction in the receiver. Under the influence of difference in pressures liquid passing through the filters fills the receiver.

Vacuum filters

They are made of filter paper of FO type (M type – filtration is slow), which retain finely dispersed precipitates are used for filtering.

Ashless filters

Glass filters N. 3 and N. 4 are widely used.

Glass filters

Modern way of purification of solutions for injections is membrane microfiltration, which allows obtaining solutions that are free from particulate matters, visible and invisible, including microorganisms, in visual inspection.

Filtration of solutions is combined with their simultaneous pouring into the prepared sterile vials.

4. PACKING

Ampoules and vials of glass, polyethylene or other materials, which do not change the properties of medicinal substances, are used.

At the chemist's shops dispensing of sterile solutions is made in wide-necked standard vials (they can be graduated) of different volume with a rubber cork fixed with the wringed aluminum.

Corks of special sorts of rubber are used for corking of the vials: IR-21 (silicon), 25P (natural rubber), 52-369, 52-369/I 52-396/II (butyl rubber), IR-119, IR-119A (butyl rubber).

Different equipment and labour-saving tools are used for rolling up and taking off the aluminum caps.

5. REGISTRATION FOR DISPENSING

Registration of solutions for injections

for outpatients

- ✓ Label of a blue colour “For injections” with the following information: number of the chemist’s shop, composition, mode of administration, release date, number of prescription;
- ✓ Additional label “Sterile”;
- ✓ Warning labels “Store in a cool, light-protected place”, “Keep out of the reach of children”;
- ✓ Label for solutions, prepared in aseptic conditions without sterilization “Prepared in aseptic conditions”.

for medioprophylactic institution

- ✓ Label of a blue colour with the following information: number of the chemist’s shop, number of hospital, department, release date, shelf life, prepared by, checked by, dispensed by, number of analysis, mode of administration, composition (in Latin).

100 ml of 0.9% sodium chloride solution were prepared according to the prescription. What sterilization schedule is required for this solution?

A. 100 ºC – 15 min
B. 120 ºC – 12 min
C. 120 ºC – 15 min
D. 120 ºC – 30 min
E. 120 ºC – 8 min

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D. 120 ºC – 30 min
E. 120 ºC – 8 min

Explanation: according to the rules of sterilization, solutions of volume 1-100 ml are sterilized during 8 min (temperature 120ºC).

A chemist's shop produces solutions for injections which must be apyrogenic. Which solution can be depyrogenised by the method of adsorption with activated carbon?

A. Atropine sulphate
B. Glucose
C. Papaverine hydrochloride
D. Scopolamine hydrobromide
E. Platyphylline hydrotartrate

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Explanation: all other substances are absorbed on the surface of activated carbon.

A pharmacist needs to sterilize 250 ml of glucose solution for injections. During how many minutes should the solution undergo sterilization (autoclave, 120ºC)?

A. 25
B. 8
C. 15
D. 12
E. 30

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A. 25
B. 8
C. 15
D. 12
E. 30

Explanation: according to the rules of sterilization, solutions of volume 101-500 ml are sterilized during 8-12 min (temperature 120ºC).

An enema can be relieved by means of hypertonic solutions. What phenomenon takes place in the blood cells after injection of such solution?

A. Plasmolysis
B. Hydrolysis
C. Hemolysis
D. Lipolysis
E. Electrolysis

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A. **Plasmolysis**
B. Hydrolysis
C. Hemolysis
D. Lipolysis
E. Electrolysis

Explanation: water comes out of the cell in order to equalize the osmotic pressure → erythrocytes loose their shape (plasmolysis).

Conclusions:

1. Characteristics of medicinal forms for injections have been generalized
2. Stages of technological process of preparing solutions for injections have been studied.
3. Filtration and packing have been reviewed.
4. Registration for dispensing has been generalized.

Thank you for your attention!