NATIONAL UNIVERSITY OF PHARMACY

TECHNOLOGY OF DRUGS DEPARTMENT

Discipline: «PHARMACY-BASED TECHNOLOGY OF DRUGS»

Technology of drops

Lecture for students of specialty "PHARMACY FOR FOREIGN STUDENTS"

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THE PLAN OF THE LECTURE

1. Definition of the medicinal form “Drops”.
2. The rules of checking doses in drops.
3. Preparation of drops.
4. Drops’ quality control and registration for dispensing.

Theoretical issue for self-study:

1. Ways od dosing device calibration.

LITERATURE

1. Chemist's technology of drugs: The manual for students of higher schools / Tikhonov A. I., Yarnykh T. G., Yurieva A. B., Garkavtseva O. A.; Edited by A. I. Tikhonov and T. G. Yarnykh. – Kharkiv: NUPh; Original, 2011. – 424 p.
2. Dry, liquid and soft medicinal forms: A textbook for English students in specialty "Pharmacy" / A. I. Tikhonov, T. G. Yarnykh, A. B. Yurieva, L. N. Podorozhna, S. S. Zuykina; Ed. by A. I. Tikhonov. – Kharkiv: NUPh; Original, 2011. – 208 p.
3. Good Pharmacy Practice (GPP) in community and hospital pharmacy settings / World Health Organization. – 1996.
4. Guidelines on the Equipment Requirements of a Retail Pharmacy Business / To facilitate compliance with Regulations 4(1) and 4(4) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
5. Guidelines to prepare for the final module control and state attestation on the discipline "Chemist's Technology of Drugs": for English students of specialty "Pharmacy": Reference edition. For individual student's work / Yarnykh T. G., Rukhmakova O. A., Buryak M. V. and others. – Kharkiv: NUPh, 2014. – p 48.
6. John F Marriott, Keith A Wilson, Christopher A Langleyv, Dawn Belcher Pharmaceutical Compounding and Dispensing. - Published by the Pharmaceutical Press. – 2010. – 288 p.
7. Tikhonov A.I., Yarnykh T.G., Yuryeva A.B., Garkavtseva O.A. Chemist's Technology of Drugs: The manual for students of higher schools / Edited by A.I. Tikhonov and T.G. Yarnykh. – Kharkiv: NUPh; Original, 2011. – 424 p.
8. United State Pharmacopeia. – XXIV ed. – Rockville: The United State Pharmacopeial, Inc., 2000. – 2569 p.
9. USP Pharmacists' Pharmacopeia. – II ed. – Rockville. The United State Pharmacopeial, Inc., 2008. – 1519 p.

1. DEFINITION OF THE MEDICINAL FORM "DROPS"

Drops – are liquid medicinal forms for internal and external use, which are dosed by drops.

Classification of drops

- by medical purpose
  - For internal use
  - For external use
    - Ophthalmic
    - Nasal
    - Dental
    - For ears
- by composition
  - Simple → one solute substance
  - Complex → two and more solute substances
- by solvent's nature
  - Water
  - Non-water

2. THE RULES OF CHECKING DOSES IN DROPS

Checking of doses for *poisonous, narcotic and strong-effective* substances in drops:

Rp.: Papaverini hydrochloride 1.0
Adonisidi 10 ml
Tincturae Convallariae
Tincturae Valerianae ana 15 ml
Mentholi 0.5
M.D.S. 30 drops 3 times a day.

1 ml of adoniside ------- 34 drops
10 ml ---------- x; x = 340 drops
1 ml of convallaria tincture ------- 50 drops
15 ml --------- x; x = 750 drops
1 ml of valerian tincture ------- 51 drops
15 ml --------- x; x = 765 drops
The total volume in drops: 340 + 750 + 765 = 1855
The number of doses: 1855 drops / 30 drops ≈ 62

Papaverine hydrochloride:
M.S.D. = 1.0 / 62 = 0.016 H.S.D. = 0.2
M.D.D. = 0.016 x 3 = 0.048 H.D.D. = 0.6
Doses are not exceeded

Adoniside:
M.S.D. = 340 drops / 62 = 5.5 dr. H.S.D. = 40 dr.
M.D.D. = 5.5 drops x 3 = 16.5 dr. H.D.D. = 120 dr.
Doses are not exceeded

Checking doses for poisonous substance in drops

Rp.: Solutionis Platyphyllini hydrotartratis 0.2 % 10 ml
D.S. 10 drops 2 times per day

Plathyphylline hydrotartrate: 0.2 ---- 100 ml
X ----- 10 ml x = 0.02
1 ml of purified water ----- 20 drops
10 ml -------- x x = 200 drops

Number of doses: 200 drops/10 drops = 20 times
Plathyphylline hydrotartrate:
M.S.D. = 0.02 / 20 = 0.001 H.S.D. = 0.01
M.D.D. = 0.001 x 2 = 0.002 H.D.D. = 0.03
Doses are not overstated

Rp.: Papaverini hydrochloride 1.0
Adonisidi 10 ml
Tincturae Convallariae
Tincturae Valerianae ana 15 ml
Mentholi 0.5
D.S. 30 drops 3 times per day

1 ml of adoniside ------- 34 drops
10 ml ---------- x; x = 340 drops
1 ml of convallaria tincture ------- 50 drops
15 ml --------- x; x = 750 drops
1 ml of valeriana tincture ------- 51 drops
15 ml --------- x; x = 765 drops
Number of doses: 1855 drops / 30 drops ≈ 62

Total volume in drops:
340 + 750 + 765 = 1855

Papaverine hydrochloride:
M.S.D. = 1.0 / 62 = 0.016 H.S.D. = 0.2
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Adoniside:
M.S.D. = 340 drops / 62 = 5.5 drops H.S.D. = 40 drops
M.D.D. = 5.5 drops x 3 = 16.5 drops H.D.D. = 120 drops

Doses are not exceeded

3. PREPARATION OF DROPS

Peculiarities of drops formulation

NB! *A small volume of drops cause the change in technological stages, mainly in straining of true solutions*

- *A medicinal substance dissolves in a half amount of solvent.*
- *The solution obtained is strained through a cotton tampon previously washed by purified water.*
- *The rest quantity of the solvent is strained through the same cotton.*

To use concentrated solutions is rational
(ophthalmic drops is an exception)!

3. PREPARATION OF DROPS USING CONCENTRATED SOLUTIONS

Is conducted directly in the bottle for dispensing

1. **Firstly measure the calculated quantity of purified water.**
2. **At the second turn measure concentrated solutions of strong-effective substances from the burette system (if they are prescribed).**

3. Then add concentrated solutions of medicinal substances from general list in the order they are prescribed in prescription.

Drops which are prepared using concentrated solutions don't need straining

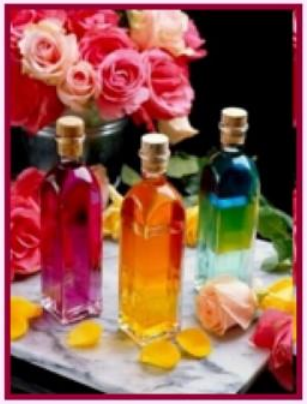
Technology of drops

- the solutions are prepare directly in the dry bottle for dispensing;
- firstly in the bottle for dispensing we place all dry substances, then solvent (water, alcohol - by volume, all others - by weight);
- in order to prevent losses the operations as filtering and straining are forbidden; for volatile medicines - the heating (flammable) is forbidden;
- the solutions on the viscous (dense), non-volatile solvents with heat-resistant substances are prepared by heating of substance together with the solvent on the water bath till 50-60°C.

1) Rp.: Acidi borici 0.3 Glycerini 10.0 M.D.S. Ear drops.	2) Rp.: Phenilii salicylatis 0.25 Olei Helianthi 10.0 M.D.S. Nose drops.

3. PREPARATION OF DROPS BY DISSOLVING DRY MEDICINAL SUBSTANCES

Rp.: Adonisidi 5 ml
Tincturae Convallariae
Tincturae Valerianae ana 10 ml
Mentholi 0.1
Kalii bromidi 2.0
M.D.S. Use 25 drops 3 times a day

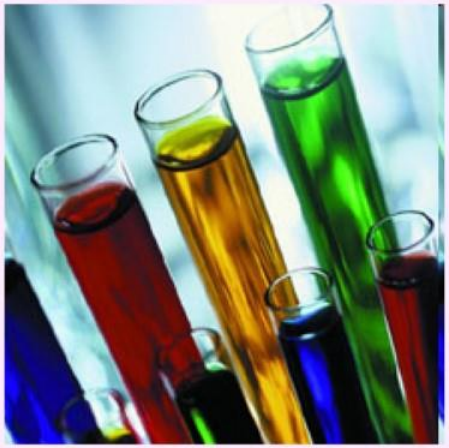


The given medicine are drops for internal use, which contain strong-effective substance – adoniside, menthol – soluble in alcohol, potassium bromide – soluble in water.

It is necessary to check doses of adoniside.

3. PREPARATION OF DROPS BY DISSOLVING DRY MEDICINAL SUBSTANCES

Directly in the bottle for dispensing measure by measuring finger 10 ml of Lily-of-the-Wally tincture and 10 ml of Valerian tincture and in this mixture dissolve 0.1 of menthol. In separate bottle measure 5 ml of adoniside and dissolve in it 2.0 of potassium bromide. Obtained solution add to the bottle for dispensing. Register for dispensing.



Technology of drops

Solutions on the viscous, non-volatile solvents with thermolabile volatile, odorous substances (menthol, camphor, phenol) are prepared by dissolving these substances into the bottle for dispensing in the solvent previously heated till 40-50°C (the order of dissolving is indicated in a front side of WCP);

Rp.: Mentholi 0.1
Olei Vaselini 10.0
M.D.S. Nose drops.

Rp.: Mentholi
Camphorae aa 0.05
Olei Vaselini 10.0
M.D.S. For inhalations.

✓ If the tooth drops are representing as eutectic alloy from several solid substances (menthol, camphor, chloral hydrate, phenylsalicylate), all dry substances place in the bottle for dispensing and put in the warm water bath (at 40°C) until complete dissolving.

4. DROPS' QUALITY CONTROL AND REGISTRATION FOR DISPENSING

Quality control →

- Written
- Asking
- Visual (colour, smell, taste)
- Dispensing

Registration for dispensing →

- "Internal" or "External"
- "Keep out of the reach of children"
- "Store in a dark cool place"
- "Shake well before use"

NB!

Drops with <u>poisonous or narcotic</u> substances are sealed up and registered for dispensing by signature and additional label "To be handled with caution"

Conclusions:

1. Definition of the medicinal form “Drops” was given.
2. The rules of checking doses in drops were considered.
3. Preparation of drops was considered.
4. Drops’ quality control and registration for dispensing were considered.

THANK YOU FOR YOUR ATTENTION!