LEC 7
PHARMACEUTICAL TECHNOLOGY
OFFICIAL SOLUTIONS

Stage: 3/ 1st course

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Define

Official solutions are liquid preparations that contain one or more chemical substances dissolved in liquid solvent, and are **mentioned in one of pharmacopeias** i.e., USP, BP, NF. For example, Iodine solution (NF).

The solvent may be water, sometimes glycerin or alcohol or mixture of solvents.

Preparation methods

There is no uniform method for preparation of official solution but each group of solutions is prepared by specific method.

According to method of preparation it can be classified into:

1. Solutions prepared by simple solution

2. Solutions prepared by chemical reaction.

3. Solutions prepared by extraction.

4. Solutions prepared by simple solution method with sterilization.

The first method is the easiest method and simplest method of preparation.

Examples of solution prepared by simple solution:

1. **Amaranth solution USP 1%:** prepared by dissolving amaranth in purified water. It is used as **coloring agent** to impart color to clear liquid preparation.

2. **Gentian violet solution USP 1%:** gentian violet in hydroalcoholic solution (10% alcohol v/v of triphenylmethane solution). It is used as **topical anti-infective**, it is used topically in undiluted form in infections caused by gram-positive bacteria or by certain parasitic fungi. *(what is the difference between disinfectant and antiseptic?)*

3. **Iodine solution NF**: it is used as **local anti-infective** for skin and surgical disinfectant.

4. **Tolnaftate solution USP 1%** in a non aqueous homogeneous vehicle of polyethylene glycol 400.

5. **Clindamycin phosphate topical solution**: used in treatment of acne vulgaris.


Iodine
Tincture USP


FungaBlend10
POWERFUL &PROVEN
What to expect during treatment.
BEFORE
AFTER
4 MONTHS
BEFORE
AFTER
6 MONTHS
BEFORE
AFTER
6 MONTHS
FungaBlend10
ANTIFUNGAL SOLUTION
Tolnaftate 1%
PODIATRIST DEVELOPED
PROFESSIONAL STRENGTH
MADE WITH 10 POTENT PLANT MEDICI
0.5 FL OZ (15ML)
Nails are fungus free when nail has grown in completely clear
fungablend10.com


Rx
Clindamycin Phosphate Topical Solution USP
Acnesol® 1%
Solution for Acne
एक्नेसोल®
25 ml
SYSTOPIC

Rx
Clindamycin Phosphate Topical Solution USP
Acnesol® 1%
Solution for Acne
एक्नेसोल®
25 ml.
SYSTOPIC


De La Cruz
Gentian Violet
1% Sol. • Alcohol 10%
First Aid Antiseptic
For External Use Only
TRUSTED QUALITY
2 FL OZ (59 mL)


Sigma-Aldrich
A1016-500G
Amaranth
Dye content 85-95 %
sigmaaldrich.com

Solution prepared by simple solution with sterilization

a. Anti-coagulants solutions. b. Irrigating solution. c. Physiologic solutions

d. Ophthalmic solutions.

Anti-coagulants:

1. Heparin solution USP sterile solution of 75,000 units of sodium heparin in sodium chloride injection. It is used 30 ml for 500 ml of whole blood.
2. Citrate-phosphate-dextrose solution: it is sterile solution consist from 3% citric acid, 26.3% sodium citrate, 2.22% sodium biphosphate and 25.5% dextrose. All these contents dissolve in water for injection; this solution is used as anti-coagulant for storage of whole blood. About 70ml of this solution should be used for 500 ml of whole blood.

Irrigating solution:

It is used to flush or bathe wounds or surgical tissues, should be sterilized because it is used for sensitive areas of the body.

Example of irrigating solution amino acetic acid sterile solution (NF): it consists from sterile solution of 1.5 and 15%, 15% requires dilution aseptically before use. 15% amino acetic acid in water for injection is used for irrigating solution in operation such that of prostate (prostatectomy).

Physiologic solutions:

Ringer's Injection, USP, is a sterile solution of sodium chloride, potassium chloride, and calcium chloride in water for injection.

The three agents are present in concentrations similar to those of physiologic fluids. Ringer's is employed as a vehicle for other drugs or alone as an electrolyte replenisher and plasma volume expander.

Lactated Ringer Injection, USP, has different quantities of the three salts in Ringer injection, and it contains sodium lactate. This injection is a fluid and electrolyte replenisher and a systemic alkalizer.

OPHTHALMIC SOLUTIONS

Sterile solutions that are applied to the eye either for **local** effect or for **treatment** of interior parts of the eye and it should be sterile, *isotonic*, *buffered* to about pH 7.4, *viscous*, and *properly packaged* and the volume either small volume or large such as in case of cleaning or for contact lenses.

Some instruction for uses of ophthalmic solutions:

1. Because the capacity of the eye to retain liquid and semisolid preparations is limited (5-10 µl), topical application are administered in small amounts. Not more than one drop is put in the eye. **If we have multiple drop therapy, there should be at least 10 min between the applications of each type.**

2. Patient should not touch the tip of the dropper with the infected eye tissue.

Requirements of ophthalmic solutions

1. Sterility and presence of anti-microbial agent (or preservatives)

- All ophthalmic solutions or most should be sterilized using **auto-clave** **at 121ºC for 15 min** except those which are unstable at the auto-clave condition, they sterilized by another method such as by using **micro-filter**, which is a physical membrane that has pore size that prevent bacteria and foreign materials from passage into ophthalmic solution. However, this method is not efficient as auto-clave method. Other methods such as using of **gases** and **rays** can also be used.

What are the methods used for ophthalmic solution sterilization?

- Ophthalmic solutions should be prepared in **aseptic area**, so all utensils and personnel should be clean and sterile, also the room should be specially designed, so that the **corner of the wall should be curvature** and also there is a **hood** pushing sterile stream of air so push all bacteria and foreign bodies outside of the room. In addition to sterility, the ophthalmic solutions of multi-dose type should contain **preservative**, so that the microorganism introduced to solution (after opening the container) accidently will show no growth.
- For ophthalmic solution used for surgical operation or for traumatized eye there is no need for preservative because: 1. they are single dose product. 2. The preservative be irritants for open eye tissue.

What are the requirements to be followed (concerning sterility) in the manufacture of ophthalmic solutions?

The properties of the preservatives used in ophthalmic solutions:

1. Should be **effective** at the used concentration.

2. Should be **inert** do not interact with active ingredient or container material.

3. **Stable**

4. Should **not adsorb** to the wall of the container.

Examples of preservative used in ophthalmic solutions:

Benzalkonium chloride which is used in concentration between 0.004-0.01% w/v.

Chlorbutanol is used in concentration 0.25-0.5% w/v.

Thiomersal used in concentration 0.001-0.5% w/v.

Methyl/propyl parabens used in concentration 0.05-0.01% w/v

2. Isotonicity

- Ophthalmic solution should be isotonic with lachrymal fluid. Isotonic mean equal tone; if the ophthalmic solution is hypertonic so when applied to eye the fluids will get out of the cell, so we have shrinkage of eye tissue, and if the ophthalmic solution is hypotonic, so swelling occur to the tissue. In both cases discomfort feeling will result, for this reason tonicity should be adjusted. Eye can tolerate practically a tonicity 0.6-2% without marked discomfort to the eye. Sodium chloride itself does not have to be used to make the solution isotonic but **boric acid** in a concentration of 1.9% is used to produce the same osmotic pressure as does 0.9% sodium chloride.

3. Buffering

Buffering of ophthalmic solutions means adjustment of ophthalmic solution pH close to **lachrymal fluid pH 7.4** as much as possible. (eye pH is 7-7.3, and its buffering capacity is 6.5-7.6).

USP described two buffers for ophthalmic solutions these are:

1. Boric acid buffer that provide pH slightly below 5, this buffer is suitable for many soluble salts of cocaine, phenylephrine, pilocarpine and tetracaine.

2. Phosphate buffer that provide a pH 5.9-8.0, it is suitable for many drugs except salt of pilocarpine, homatropine because they are unstable in this buffer.

4. Viscosity

- Ophthalmic solutions should be viscous enough, so the drug will be in contact with eye tissue for a long period of time and **prevent drainage of ophthalmic solutions**. So a suitable viscosity enhancing agent is used as 1% methyl cellulose, which gives viscosity 25 cps. This substance is also used as tear replacement. The optimal viscosity for ophthalmic solution is between **15 to 25 cps.**

5. Proper packaging

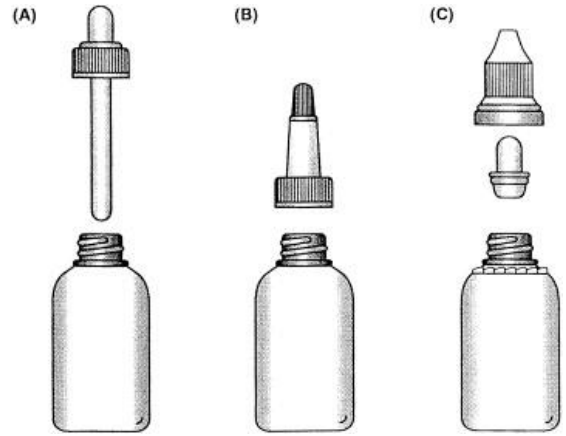
The important thing is the product should be packed in a container, so the solution is easily administrated, active constituents are stable and the sterility is maintained.

We have two types of containers:

1. Glass containers

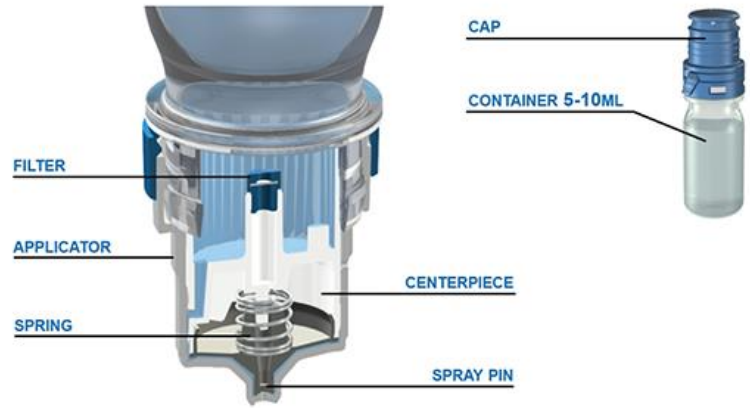
2. Plastic containers

- The disadvantage of **glass** containers is that the **alkaline substance is leached from the glass container to ophthalmic solution** causing an increase in the pH of the solution.
- The disadvantage of the **plastic** container is the **interaction of the substance of the container with the preservative** used or it allow separation of some medicinal agents.


(A)
(B)
(C)


Beautiful Garden
Rose Water
AUTHENTIC, HOME MADE
& CHEMICAL FREE EYE DROP


alamy
alamy


CAP
CONTAINER 5-10ML
FILTER
APPLICATOR
CENTERPIECE
SPRING
SPRAY PIN

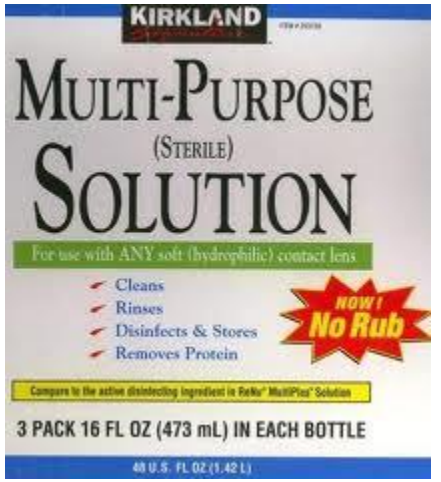
- The dropper of ophthalmic solution is either **fixed dropper** or **screw dropper**. Fixed dropper is better because there is a low chance for microorganism to be introduced into the solution. The solvent used should be sterile distilled water or water for injection.
- Contact lenses solutions: contact lenses may be hard, soft or rigid gas permeable (RGP). Solution which are used for taking care of contact lenses are used as wetting solutions, cleaning solutions, soaking solutions or combined purpose solutions. It is very important to take care of contact lenses, if we do not take care of them then infection will takes place and if it occurs this may result in different problems, also if the lenses are not clean then it modify the sight.


Soft Eye
Soft Eye
Soft Eye
Soft Eye
Soft Eye
Soft Eye


CONTACT LENS SOLUTION
Beauty


Contact lens solutions
CONTACT
LENS
Solution

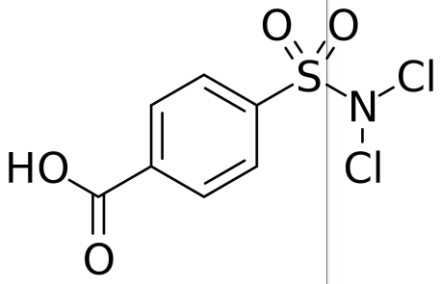

TWIN PACK 2-16 FL. OZ.
CLEAR CARE
NO RUB
CLEAR CARE
NO RUB
CLEAR CARE


KIRKLAND
MULTI-PURPOSE
(STERILE)
SOLUTION
For use with ANY soft (hydrophilic) contact lens
Cleans
Rinses
Disinfects & Stores
Removes Protein
NOW! No Rub
3 PACK 16 FL OZ (473 mL) IN EACH BOTTLE

Official solutions prepared from tablets

Halazone tablets for solution USP

(4mg of halazone).



Uses

Disinfectant

For the sterilization of drinking water

1 or 2 tablets per liter

The tablets should be labeled to indicate that they are not intended to be swallowed.

Potassium permanganate tablet for solution USP 60

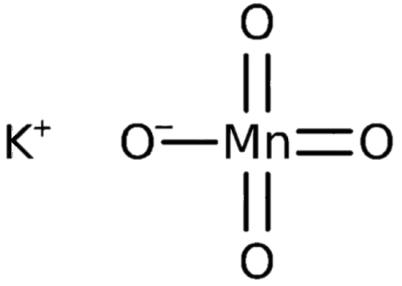
125 and 300 mg of potassium permanganate

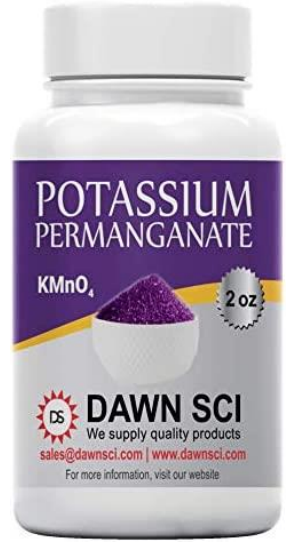
Uses Topical anti-infective

Applied topically to the skin and mucous membranes as 0.004 to 1% solution or in a wet dressing

preparing this solution. Only distilled water should be used in, why?

Since potassium permanganate is incompatible with organic materials such that might be present in tap water, only distilled water should be used in preparing solution of it





THANK YOU

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