31.8.4. Quality Control Tests in Parenteral Preparations

Unlike other preparations, in parenteral preparations;

- Sterility (EP 5)
- Pyrogen (EP 5)
- Particulate contamination (EP 5)
- Extractable volume (EP 5)
- Packing integrity (crack)

tests are being conducted.

Small Volume Parenteral Preparations

Practice 31.1.

Dextrose Injection (USP 27)

D-Glucose monohydrate		5.0 g
Saturated potassium chloride solution		0.3 ml
Water for injection	q.s.	100.0 ml

Prepare 5 ml ampoules.

Molecular weight of D-glucose monohydrate (dextrose): 198.17

Preparation:

D-glucose monohydrate is dissolved in a mixture of water and saturated potassium chloride solution. It is filtered through porcelain, membrane or glass filter. The empty ampoules are washed in the ampoule washing machine and dried in an oven. Then, a 10% excess of the required amount of the prepared solution (5.5 ml) is calculated and filled into the ampoules with a syringe. (Care should be taken to avoid contamination of the neck of the ampoule while it is being filled). The filled ampoules are closed by pulling with a clamp after the neck part of ampoules are heated in the hammer. They are sterilized in an autoclave at 110 ° C for 40 minutes. The hot ampoules removed from the autoclave are immediately immersed in a 0.5% cold methylene blue solution while the necks of ampoules are kept below, then washed out and visually checked for color and clarity. Labeled properly.

Questions:

1. In what way and for what purpose is this solution used?
2. Calculate the osmotic pressure of this solution.

Why do you immersed the ampoules into the methylene blue solution after sterilization?

3. Which product is occured by the degradation of glucose and how is it occured? How do you prevent this product from forming?

Practice 31.2.

Sodium Novamine Sulphonate Solution for Injection

(General and Industrial Pharmaceutical Technology Student Experimental Studies - 1985)

Prepare 2 ml ampoules containing 50% sodium novamine sulfonate.

Preparation:

In a conical flask, 6 ml, 50% w/v sodium novamine sulphonate solution is prepared with sterile water for injection. It is filtered through porcelain, membrane or glass filter. The filtrate is separated into two portions and 0.1% sodium metabisulfite is added to an half. One of the prewashed dried ampoules is filled by the solution containing sodium metabisulphite and the other is filled by the solution without sodium metabisulphite, with a syringe. A 10% excess (2.1 ml) of the required amount of the prepared solution should be filled into the ampoules. The ampoules are sealed and sterilized for at least 15 min at 121° C and under 1 atm pressure in an autoclave. The hot ampoules are immediately immersed in a 0.5% methylene blue solution, washed out, and visually checked for color and clarity. Labeled properly.

Questions:

1. Describe the reasons for the addition of sodium metabisulphite to ampoules. What are the differences between the two solutions after removal from the autoclave?
2. Why are 2 ml ampoules filled with 2.1 ml solution?
   What type of ampoules are used for this preparation? Why?

32.3. Ear Preparations

Practice 32.13.

Benzocaine-Antipyrin Ear Drop

Antipyrine		0.3 g
Benzocaine		1.0 g
Glycerine	q.s.	30.0 ml

Preparation:
After the benzocaine and antipyrine is thoroughly dusted in the mortar, the powder is dissolved on the water-bath by mixing with glycerin. The solution is filtered by using cheesecloth and completed to 30 ml in the graduated cylinder. It is labeled in a suitable bottle.

Questions:
1. Please explain the reason why water is not used as a solvent in ear drops.
2. Describe the intended use and daily dose of this preparation.