Standards For water

- **Types of water**

i. Water (U.S.P)
ii. Purified water (U.S.P)
iii. Water for Injection (U.S.P)
iv. Sterile water for injection
v. Bacteriostatic water for injection

I. Water (U.S.P): Pharmaceutical manufacturers are permitted to use it. It can be used in drinking, washing, extracting crude drug, preparation of certain products for external use.

Characters of water (U.S.P)

It not suitable for general pharmaceutical use because of considerable amount of residue not more than 0.1% (100 mg/100 ml). This is obtained by evaporation to dryness on steam bath and subsequent drying at 105 C° and weighing the residue .

Residue consists of salt: such as Ca^{+2} ,K^{+}, SO_4^{-2},HCO_3^{-},Mg^{+2},NH_3 salts.

The major objection to use water (U.S.P) in pharmaceutical preparations is the ability to precipitate these salts at high temperature.

♣ Water (U.S.P) is odourless, tasteless, pH neutral, colorless, slightly alkaline (deviation from alkalinity to acidity is due to the decomposition of solids and also the dissolved CO_2 contributing to acidity and Ammonia (NH_3) to the alkalinity.

II. Purified water (U.S.P)

Is used in preparation of all medications containing water except ample, injection, and some official external preparations such as liniments and other special products.

Purified water (distilled water) may be prepared by distillation, ion exchange, Reverse osmosis.

1. Distillation

Many stills in various sizes and styles with capacities ranging from about 0.5 to 100 gallons of distillate per hour are available to prepare Purified water. Generally the first portion should be discarded since it contain many foreign and volatile substances usually found in urban drinking water also the last portion must be discarded residue will compose 10% of original volume, and should not be subjected to further distillation to dryness because it will result in decomposition of the remain solid impurities that may that may be distillated and contaminate the previously collected distillated water.

Note: pH of freshly D.W is 5.6 – 6.0 on the storage it may be rendered by boiling it to free CO2 in the D.W.

2. Ion exchange

Advantages

- Eliminate use of heat
- Simpler equipment's with less maintenance
- Lower long – term cost
- Ease of production

Procedure: it involves * the passage of water through a column of cation and anion exchanger consisting of water insoluble synthetic, *polymerized phenolic carboxylic amino or sulfonated resins of high M wt.

* These resins are mainly of 2 types:

A) The cation (Acid exchangers) which permit exchange of the cations in solution (in the tap water) with hydrogen ion from the resin (remove the anion from water)

B) The anion (base exchangers) remove the cations from the water (cation are fixed with resins due to H_2 replacement with cations salt.

Cation such as Na^+, anion such as CL^-

It can be simplified

1. The cation step in exchanger

   H^+ -- Resin + M^+ +X^- + H_2O ⟶ M^+ --- Resin + H^+ + X^- + H_2O(pure)

   M+ , X^- : anion and cation present in salts of the solution(water)

2. The anion step : The water is passed through a basic resin after the cation step (the basic resin is usually polyamine used to remove X^-) X^- remain in water is removed according to equation

$Resin – NH_2 + H^+ + X^- + H_2O$ ⟶ $Resin – NH_2 . HX + H_2O$(pure) OR

$Resin – NH_3OH + H^+ + X^-$ ⟶ $Resin – NH_3X + H_2O$

Water purified in this manner is referred as demineralized or de ionized water.

Note: cartilage of mixed resins filled into the top of polyethylene bottle provide a simple mean for readily converting tap water in purified water.

3. Reverse Osmosis

In this method pressurized water stream is passed parallel to inner of filter membrane core. A portion of water (feed water) will pass through permit the membrane as filtrate while the balance of water sweeps tangentially along the membrane to exit the system without being filtrated the filtrate portion called permeate, the infiltrated portion which pass without filtrate is called concentrate why? Because it contains concentrated contaminates rejected by the membrane.

Note: in osmosis from less concentration to high concentration area

In reverse osmosis from high concentration to the less concentration depending cross flow.

III. Water for Injection (U.S.P)

Should be pyrogen free used for parental preparations and its use as a solvent only in solution that are to be sterile after preparation, use as parental solution solvent under

aseptic condition in this case it should be isotonic too (adding 0.9% NaCl) with body fluid only in pyrogen test this is achieved by process of sterilization.

Sterilization

Process of freeing of material from all living organisms and their spores, this accomplished by various ways but the most preferred is the USP XIII process steam under pressure (Autoclave). If Autoclave is not available freshly distilled water is sterilized by boiling for at least 60 min in a flask stoppered with plug of purified nonabsorbent cotton cover with gauze or flask peek may be covered by cellophane and tightly fastened with cord the water is allowed to cool without removing the stopper.

Pyrogen

Are fever producing substances probably of bacterial origin they consist of lipo poly saccharide from outer cellular wall of bacteria and endotoxins they may be thermo liable D.W pyrogen are produced as specific bacteria that grow in water and are nonvolatile. Bacteria can grow in D.W in shape of pyrogen substance some of these materials are organic material it can be removed by oxidation then to easily eliminate gases and nonvolatile materials by functional distillation using $Kmno_4$ to increase the efficiency by adding barium hydroxide to increase alkalinity and convert it to barium salt any various substance it more efficient and result in highly sterile and pyrogen free water, pyrogen and bacterial relative filters are widely used for sterilization water from immediate use must be distilled and sterilized with in 24 hrs. (tightly closed in temperature above that of bacterial growth and use U.V light to prevent it) , must not be stored for more than 24 hrs.

Reference text: Pharmaceutical Dosage forms and Drug Delivery Systems By Haward A. Ansel; latest edition. and Sprowel's American Pharmacy.