*WATER

*Water is the best polar universal solvent.

*Natural water is never totally pure. No matter how it is isolated, it always has some dissolve chemicals.

*Natural water is true sense of mineral water, due to suspended colloidal solids like dust, dirt, microorganism & dissolve electrolytes.

*Some dissolve material gives water a characteristic taste.

*Water uniqueness is due to its ability to form strong hydrogen bonds with other water molecule or other electronegative or positive ions of molecule.

*Properties of water

*Physical properties:

*Density of ice is less than density of liquid water. That's how ice floats on water.

*Water has high specific heat

*1. Turbidity: turbidity refers to the cloudiness of the water. It can be problem in surface- water sources.

*2. Color: A physical characteristics of water that is not notices unless its color is very concentrated.

*3. Dissolved solids: the total dissolved solids can have a significant impact on the quality of water.

*Chemical properties:

*Chemically it is considered amphoteric in nature.

*It can act as acid or base in presence of base or acid respectively.

*Types of water

*1. Purified water IP

- *Clear, colorless liquid; odorless & tasteless.
- *Purified water, IP, is prepared by distillation, by means of ion exchange, by any other appropriate means from suitable potable water.
- *During production & storage, appropriate measures are taken to ensure that the total viable aerobic count is adequately controlled & monitored. Limit of total viable aerobic count is 100 microorganism per milliliter, determined by membrane filtration, using agar medium S & incubating at 30-35 C for 5 days.
- *Clear colorless liquid; odorless & tasteless.

*Quality control test

* Test for purity:

*1. limit of total viable aerobic count is 100 microorganism per ml determined by membrane filtration.

***Acidity or alkalinity:** to 10ml of(freshly boiled & cooled in a borosilicate glass flask) add 0.05 ml of methyl red solution, the resulting solution should not be red. To 10ml add 0.1 ml of bromothymol blue solution, the resulting solution should not be blue.

***Calcium & magnesium:** To 100ml, add 2ml of ammonia buffer PH 10.0, 50 mg of mordant black II mixture & 0.5 ml of 0.01 M disodium edetate; a pure blue color should be produced.

***Heavy metals:** Not more than 0.1 ppm, determined on 12 ml of a solution prepared by evaporating 150ml to 15ml on a water- bath.

* **Chloride:** To 10ml add 1ml of 2M nitric acid & 0.2 ml of 0.1 M silver nitrate; the appearance of the solution should not change for at least 15 min.
* **Oxidizable substances:** 100ml water, 10ml 1M H_2SO_4, 0.1 ml $KMnO_4$, boil for 5min. Solution should remains faintly pink.
* **Residue on evaporation:** Evaporate 100ml to dryness on a water- bath & dry to constant weight at 105 C. the residue weight not more than 1 mg.
* **Storage:** Store in well closed container. The material of container should not alter the properties of the water.

*2. Water for injection IP:

Water for injection IP 2007, is apyrogenic, distilled water, intended for use in the preparation of medicines for parenteral administration.

Here, water is used as a vehicle & for dissolving or diluting substances, or preparation for injectable preparation (sterile water for injection).

Water for injection is obtained by distilling potable water, or purified water, from a neutral glass, quartz, or suitable metal, still fitted with an effective device for preventing the entrainment of droplets; the still must be suitably maintained to ensure the production of apyrogenic water.

the first portion of the distillate is discarded & the remainder is collected & stored in conditions designed to prevent the growth of microorganism & to avoid any other contamination.

*Quality control test

*Test for purity:

*Total organic carbon: Maximum 0.5 mg/l

*Conductivity: Determined by using conductometer.

*Appearance: Clear & colorless liquid.

*Nitrates: Maximum 0.2 ppm.

*Aluminium: Maximum 10 ppb.

*Heavy metals: Maximum 0.1 ppm

*Bacterial endotoxins: Less than 0.25 IU/ml.

*3. Sterile water for injection IP

*Sterile water for injection as per IP, is water for injection distributed in suitable containers of glass or any other material, sealed & sterilized by heat, under conditions that ensure that the water remains apyrogenic.

*Each container contains a sufficient quantity of water for injection to permit the withdrawal of the nominal volume. It is clear, colorless & odourless liquid.

*The test for purities given under purified water are applicable to sterile water for injection with appropriate modification.

*Quality control test

- ***Test for purity:**
- ***Clarity & color:** When examined in suitable conditions of visibility, it is clear, colorless & practically free from suspended particles.
- ***Acidity & alkalinity:** To 20ml add 0.05ml of phenol red solution. If the solution is yellow, it becomes red on the addition of 0.1 ml of 0.01M sodium hydroxide; if red becomes yellow on the addition of 0.15ml of 0.01M hydrochloric acid.
- ***Bacterial endotoxins:** Not more than 0.25 endotoxin unit per ml.
- ***Sterility:** Complies with the test for sterility.
- ***Residue on evaporation:** residue should not be more than 3mg
- ***Storage:** Store in single dose container of not larger than one liter size.

*4. Bacteriostatic water for injection

*Not included in IP/BP, but included in USP

*As per USP, it is sterile water for injection, to which one or more suitable antimicrobial preservatives are added.

*It is used in the parenteral preparations as diluents.

*It is used in those parenteral preparations where multiple withdrawals are necessary. It is packed in single or multi dose containers, not larger than 30 ml.

*Quality control test

- ***Test for purity:**
- ***Antimicrobial agent:** Must conform to label claims.
- ***PH:** Between 4.5 & 7.0
- ***Carbon dioxide:** When to 25ml, 25ml of calcium hydroxide solution is added, solution remains clear.
- ***Particulate matter:** >10 micrometer: 3000 particles & >22 micrometer: 300 particles per container.
- ***Bacterial endotoxins:** Should contain less than 0.5 USP endotoxin unit/ml.
- ***Calcium:** To 100ml add 2ml ammonium oxalate solution. It should not produce any turbidity.
- ***Sulphate:** To 100ml add 1ml barium chloride solution. No