Purified water (Aqua purificata)

H_2O

Relative molecular mass. 18.02

Chemical name. Water; CAS Reg. No. 7732-18-5.

Description. A clear, colourless liquid; odourless.

Category. Solvent.

Storage. Purified water should be kept in a well-closed container.

Labelling. The designation on the container should indicate the method of preparation.

Additional information. *CAUTION*:

- Purified water must not be used for preparations intended for parenteral administration.

- Purified water intended for ophthalmic preparations must be sterilized immediately before use (see 3.2 Test for sterility and 5.8 Methods of sterilization.

Requirements

Definition. Purified water contains no added substance.

Manufacture. Purified water is prepared by distillation, ion-exchange treatment, reverse osmosis, or other appropriate process from suitable water.

Heavy metals. Use 40 mL, adjust the pH with acetic acid (~60 g/l) PbTS and proceed as described under 2.2.3 Limit test for heavy metals, procedure 1; determine the heavy metals content according to Method A, allowing to stand for 10 minutes; the colour is not darker than that of 40 mL of the same untreated Purified water, the pH of which has been similarly adjusted.

Ammonia. Transfer 50 mL to a comparison tube, add 2 mL of alkaline potassio-mercuric iodide TS, and observe down the vertical axis of the tube in diffused light against a white background; the colour produced is not more intense than that of 50 mL of ammonia-free water R with the addition of 2 mL of dilute ammonium chloride TS.

Calcium and magnesium. To 100 mL add 2 mL of ammonium chloride buffer, pH 10.0, TS, 50 mg of mordant black 11 R, and 0.5 mL of disodium edetate (0.01 mol/l) VS; a pure blue colour is produced.

Carbon dioxide. To 25 mL add 25 mL of calcium hydroxide TS; it remains clear.

Chlorides. To 10 mL add 1 mL of silver nitrate (40 g/l) TS and allow to stand for 5 minutes; it remains clear and colourless.

Nitrates. Carefully superimpose 5 mL on 5 mL of diphenylamine/sulfuric acid TS, ensuring that the liquids do not mix; no blue colour appears at the interface of the two liquids.

Sulfates. To 10 mL add 1 mL of barium chloride (50 g/l) TS and allow to stand for 5 minutes; it remains clear and colourless.

Oxidizable matter. To 100 mL add 10 mL of sulfuric acid (~100 g/l) TS and 0.5 mL of potassium permanganate (10 g/l) TS and boil for 3 minutes; the colour is not completely destroyed.

Non-volatile residue. Evaporate 500 mL on a water-bath to dryness and dry the residue for 1 hour at 105 °C; not more than 5 mg (0.01 mg/mL).

Acidity or alkalinity. To 10 mL add 2 drops of methyl red/ethanol TS; a red colour does not appear. To a further 10 mL portion add 5 drops of bromothymol blue/ethanol TS; no blue colour develops.

Additional requirement for Purified water for sterile use

Complies with 3.2 Test for sterility.