total organic carbon and, in determination of total organic carbon in a solution of sodium dodecylbenzenesulfonate (33.22 mg/L), not less than 1.7 mg/L. For the calibration of the apparatus use potassium hydrogen phthalate (standard reagent).

(9) Residue on evaporation—Evaporate 100 mL of Water for Injection, and dry the residue at 105°C for 1 hour: the residue weighs not more than 4.0 mg for Distilled Water for Injection in a volume not more than 10 mL, and not more than 3.0 mg for that exceeding 10 mL.

Bacterial endotoxins Less than 0.25 EU/mL.

Sterility test Perform the test with Water for Injection preserved in containers and sterilized: it meets the requirements of the Sterility Test. For sterilized Water for Injection in containers holding a volume exceeding 100 mL, perform the test according to the Membrane filtration method.

Containers and storage Containers—**(1)** For the preparation of injections, suitable containers, protected from microbial contamination.

(2) Hermetic containers for Water for Injection, previously sterilized in containers. Plastic containers for aqueous infusions may be used.

Purified Water

精製水

H_2O: 18.02

Purified Water is water purified by distillation, ion-exchange treatment, ultrafiltration or combination of these methods. In case the ion-exchange treatment is used at the end of the purification process, be careful to prevent bacterial contamination, and, if necessary, kill or remove bacteria by a suitable method.

Use immediately after purification. It may be stored in suitable containers preventing bacterial growth.

Description Purified Water is a clear, colorless liquid. It is odorless and tasteless.

Purity **(1)** Acid or alkali—To 20 mL of Purified Water add 0.1 mL of methyl red TS for acid or alkali test: a yellow to orange color develops. To 20 mL of Purified Water add 0.05 mL of bromothymol blue TS: no blue color develops.

(2) Chloride—To 50 mL of Purified Water add 3 drops of nitric acid and 0.5 mL of silver nitrate TS: no change occurs.

(3) Sulfate—To 50 mL of Purified Water add 0.5 mL of barium chloride TS: no change occurs.

(4) Nitrogen from nitrate—Transfer 2.0 mL of Purified Water to a 50-mL beaker, add 1 mL of sodium salicylate-sodium hydroxide TS, 1 mL of a solution of sodium chloride (1 in 500) and 1 mL of a solution of ammonium amidosulfate (1 in 1000), and evaporate on a water bath to dryness. Cool, dissolve in 2 mL of sulfuric acid, allow to stand for 10 minutes with occasional shaking, add 10 mL of water, and transfer to a Nessler tube. Cool, add 10 mL of a solution of sodium hydroxide (2 in 5) slowly, and add water to make 25 mL: no yellow color develops.

(5) Nitrogen from nitrite—Transfer 10 mL of Purified Water to a Nessler tube, and add 1 mL of a solution of sulfanilamide in dilute hydrochloric acid (1 in 100) and 1 mL of *N*-(1-naphthyl)-*N'*-diethylethylenediamine oxalate TS: no pale red color develops.

(6) Ammonium—Perform the test as directed under the Ammonium Limit Test, using 30 mL of Purified Water as the test solution. Prepare the control solution as follows: to 0.15 mL of Standard Ammonium Solution add purified water for ammonium limit test to make 30 mL, and proceed in the same manner as the test solution (not more than 0.05 mg/L).

(7) Heavy metals—The 40 mL of Purified Water add 2 mL of dilute acetic acid and 1 drop of sodium sulfide TS: no change occurs.

(8) Potassium permanganate-reducing substances—To 100 mL of Purified Water add 10 mL of dilute sulfuric acid, boil, add 0.10 mL of 0.02 mol/L potassium permanganate VS, and boil again for 10 minutes: the red color does not disappear.

(9) Residue on evaporation—Evaporate 100 mL of Purified Water on a water bath to dryness, and dry the residue at 105°C for 1 hour: the amount of the residue is not more than 1.0 mg.

Containers and storage Containers—Tight containers.

Sterile Purified Water

滅菌精製水

Sterile Purified Water is sterilized Purified Water. It is not to be used for preparation of injections.

Description Sterile Purified Water is a clear, colorless liquid. It is odorless and tasteless.

Purity **(1)** Acid or alkali—To 20 mL of Sterile Purified Water add 0.1 mL of methyl red TS for acid or alkali test: a yellow to orange color develops. To 20 mL of Sterile Purified Water add 0.05 mL of bromothymol blue TS: no blue color develops.

(2) Chloride—To 50 mL of Sterile Purified Water add 3 drops of nitric acid and 0.5 mL of silver nitrate TS: no change occurs.

(3) Sulfate—To 50 mL of Sterile Purified Water add 0.5 mL of barium chloride TS: no change occurs.

(4) Nitrogen from nitrate—Transfer 2.0 mL of Sterile Purified Water to a 50-mL beaker, add 1 mL of sodium salicylate-sodium hydroxide TS, 1 mL of a solution of sodium chloride (1 in 500) and 1 mL of a solution of ammonium amidosulfate (1 in 1000), and evaporate on a water bath to dryness. Cool, dissolve in 2 mL of sulfuric acid, allow to stand for 10 minutes, with occasional shaking, add 10 mL of water, and transfer to a Nessler tube. Cool, add 10 mL of a solution of sodium hydroxide (2 in 5) slowly, and add water to make 25 mL: no yellow color develops.

(5) Nitrogen from nitrite—Transfer 10 mL of Sterile Purified Water to a Nessler tube, and add 1 mL of a solution of sulfanilamide in dilute hydrochloric acid (1 in 100) and 1 mL of *N*-(1-Naphthyl)-*N'*-diethylethylenediamine oxalate TS: no pale red color develops.