

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

H₂O: 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.

(6) Ammonium—Perform the test as directed under the Ammonium Limit Test, using 30 mL of Sterile 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—To 40 mL of Sterile 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 Sterile 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 Sterile Purified Water on a water bath to dryness, and dry the residue at 105°C for 1 hour: the mass of the residue is not more than 1.0 mg.

Sterility Take 500 mL of Sterile Purified Water, and perform the test by the Membrane filtration method: it meets the requirements of the Sterility Test.

Containers and storage Containers—Containers used at the time of sterilization.

Storage—Protected from microbial contamination.

Weil's Disease and Akiyami Combined Vaccine

ウイルス病秋やみ混合ワクチン

Weil's Disease and Akiyami Combined Vaccine is a liquid for injection containing inactivated Weil's disease leptospira, Akiyami A leptospira, Akiyami B leptospira and Akiyami C leptospira. The product lacking more than a kind of Akiyami leptospira may be prepared, if necessary.

It conforms to the requirements of Weil's Disease and Akiyami Combined Vaccine in the Minimum Requirements for Biological Products.

Description Weil's Disease and Akiyami Combined Vaccine is a white-turbid liquid.

Wheat Starch

Amylum Triticum

コムギデンプン

Wheat Starch consists of the starch granules obtained from the seeds of *Triticum aestivum* Linné (*Gramineae*).

Description Wheat Starch occurs as white masses or powder. It is odorless and tasteless.

Under a microscope, Wheat Starch appears as spherical or

lenticular simple grains in various sizes ranging from 5 to 60 μm , mostly 25 to 35 μm . Hilum and striation are indistinct.

It is practically insoluble in water and in ethanol (95).

Identification (1) To 1 g of Wheat Starch add 50 mL of water, boil, and allow to cool: a turbid, neutral and pasty liquid is formed.

(2) To a portion of Wheat Starch add iodine TS: a dark blue-purple color is produced.

Purity Foreign matter—Under a microscope, Wheat Starch does not contain starch grains of any other origin. It may contain a minute quantity, if any, of fragments of the tissue of the original plant.

Loss on drying Not more than 15.0% (6 hours).

Total ash Not more than 1.0%.

White Ointment

白色軟膏

Method of preparation

Purified Lanolin	50 g
White Beeswax	50 g
White Petrolatum	a sufficient quantity

To make 1000 g

Prepare as directed under Ointments, with the above materials.

Description White Ointment is white in color. It has a slight, characteristic odor.

Containers and storage Containers—Tight containers.

Whole Human Blood

人全血液

Whole Human Blood is a liquid for injection which is prepared by mixing human blood cells and an anticoagulant solution for storage.

It conforms to the requirements of Whole Human Blood in the Minimum Requirements for Biological Products.

Description Whole Human Blood is a deep red liquid from which the erythrocytes settle upon standing, leaving a yellow supernatant layer. A gray layer which mainly consists of leucocytes may appear on the surface of the settled erythrocyte layer. The supernatant layer may become turbid in the presence of fat, or may show the faint color of hemoglobin.