

nia TS, and allow to stand for 5 minutes: no red color is produced.

(6) **Arsenic**—Prepare the test solution with 1.5 g of Xylitol according to Method 1, and perform the test using Apparatus B (not more than 1.3 ppm).

(7) **Sugars**—Dissolve 5.0 g of Xylitol in 15 mL of water, add 4.0 mL of dilute hydrochloric acid, and heat in a water bath for 3 hours under a reflux condenser. After cooling, neutralize with sodium hydroxide TS (indicator: 2 drops of methyl orange TS). Then add water to make 50 mL, transfer 10 mL of this solution to a flask, add 10 mL of water and 40 mL of Fehling's TS, boil gently for 3 minutes, and allow to stand to precipitate copper (I) oxide. Remove the supernatant liquid through a glass filter (G4), and wash the precipitate with warm water until the last washing does not show alkalinity. Filter these washings through the glass filter mentioned above. Dissolve the precipitate in the flask in 20 mL of iron (III) sulfate TS, filter the solution through the glass filter mentioned above, wash with water, combine the washings with the filtrate, heat at 80°C, and titrate with 0.02 mol/L potassium permanganate VS: not more than 1.0 mL of 0.02 mol/L potassium permanganate VS is consumed.

**Loss on drying** Not more than 1.0% (1 g, in vacuum, phosphorus (V) oxide, 24 hours).

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.2 g of Xylitol, previously dried, dissolve in water to make exactly 100 mL. Pipet 10 mL of this solution into an iodine flask, add 50 mL of potassium periodate TS exactly, and heat in a water bath for 15 minutes. After cooling, add 2.5 g of potassium iodide, stopper, shake well, allow to stand for 5 minutes in a dark place, and titrate with 0.1 mol/L sodium thiosulfate VS (indicator: 3 mL of starch TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium thiosulfate VS  
= 1.9018 mg of C<sub>5</sub>H<sub>12</sub>O<sub>5</sub>

**Containers and storage** Containers—Tight containers.

## Xylitol Injection

キシリトール注射液

Xylitol Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of xylitol (C<sub>5</sub>H<sub>12</sub>O<sub>5</sub>; 152.15).

**Method of preparation** Prepare as directed under Injections, with Xylitol. No preservative may be added.

**Description** Xylitol Injection is a clear, colorless liquid. It has a sweet taste.

**Identification** Measure a volume of Xylitol Injection, equivalent to 0.1 g of Xylitol according to the labeled amount, add water to make 10 mL, and use this solution as the sample solution. Separately, dissolve 0.1 g of xylitol in 10 mL of water, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 2 μL each of the sample solution and the standard solution on a plate of silica gel

for thin-layer chromatography. Develop the plate with a mixture of ethanol (95), ammonia solution (28) and water (25:4:3) to a distance of about 10 cm, and air-dry the plate. Spray evenly silver nitrate-ammonia TS, and dry at 105°C for 15 minutes: the spots from the sample solution and the standard solution show a blackish brown color and the same R<sub>f</sub> value.

**pH** 4.5 – 7.5

**Bacterial endotoxins** Less than 0.50 EU/mL.

**Assay** Measure exactly a volume of Xylitol Injection, equivalent to about 5.0 g of xylitol (C<sub>5</sub>H<sub>12</sub>O<sub>5</sub>) according to the labeled amount, and add water to make exactly 250 mL. Measure exactly 10 mL of this solution, and add water to make exactly 100 mL. Then, pipet 10 mL of this solution into an iodine flask, and proceed as directed in the Assay under Xylitol.

Each mL of 0.1 mol/L sodium thiosulfate VS  
= 1.9018 mg of C<sub>5</sub>H<sub>12</sub>O<sub>5</sub>

**Containers and storage** Containers—Hermetic containers.

## Zinc Oxide

酸化亜鉛

ZnO: 81.39

Zinc Oxide, when ignited, contains not less than 99.0% of ZnO.

**Description** Zinc Oxide occurs as a white, amorphous powder. It is odorless and tasteless.

It is practically insoluble in water, in ethanol (95), in acetic acid (100) and in diethyl ether.

It dissolves in dilute hydrochloric acid and in sodium hydroxide TS.

It gradually absorbs carbon dioxide from air.

**Identification (1)** Heat Zinc Oxide strongly: a yellow color develops on strong heating, and disappears on cooling.

(2) A solution of Zinc Oxide in dilute hydrochloric acid (1 in 10) responds to the Qualitative Tests for zinc salt.

**Purity (1)** Carbonate, and clarity and color of solution—Mix 2.0 g of Zinc Oxide with 10 mL of water, add 30 mL of dilute sulfuric acid, and heat on a water bath with stirring: no effervescence occurs, and the solution obtained is clear and colorless.

(2) **Alkali**—To 1.0 g of Zinc Oxide add 10 mL of water, and boil for 2 minutes. Cool, filter through a glass filter (G3), and to the filtrate add 2 drops of phenolphthalein TS and 0.20 mL of 0.1 mol/L hydrochloric acid VS: no color develops.

(3) **Sulfate**—Shake 0.5 g of Zinc Oxide with 40 mL of water, and filter. Take 20 mL of the filtrate, add 1 mL of dilute hydrochloric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.096%).

(4) Iron—Dissolve 1.0 g of Zinc Oxide in 50 mL of diluted hydrochloric acid (1 in 2), dissolve 0.1 g of ammonium peroxodisulfate in this solution, and extract with 20 mL of 4-methyl-2-pentanone. Add 30 mL of acetic acid-sodium acetate buffer solution for Iron Limit Test, pH 4.5, to the 4-methyl-2-pentanone layer, extract again, and use the layer of the buffer solution as the test solution. Separately, perform the test in the same manner with 1.0 mL of Standard Iron Solution, and use the layer so obtained as the control solution. Add 2 mL each of L-ascorbic acid solution for Iron Limit Test (1 in 100) to the test solution and the control solution, respectively, mix, allow to stand for 30 minutes, add 5 mL of an ethanol (95) solution of  $\alpha, \alpha'$ -dipyridyl (1 in 200) and water to make 50 mL. After allowing to stand for 30 minutes, compare the color of the both liquids against a white back: the color of the liquid from the test solution is not stronger than that from the control solution (not more than 10 ppm).

(5) Lead—To 2.0 g of Zinc Oxide add 20 mL of water, then add 5 mL of acetic acid (100) with stirring, and heat on a water bath until solution is complete. Cool, and add 5 drops of potassium chromate TS: no turbidity is produced.

(6) Arsenic—Dissolve 0.5 g of Zinc Oxide in 5 mL of dilute hydrochloric acid, use this solution as the test solution, and perform the test using the Apparatus B (not more than 4 ppm).

**Loss on ignition** Not more than 1.0% (1 g, 850°C, 1 hour).

**Assay** Weigh accurately about 0.8 g of Zinc Oxide, previously ignited at 850°C for 1 hour, dissolve in 2 mL of water and 3 mL of hydrochloric acid, and add water to exactly 100 mL. Pipet 10 mL of this solution, add 80 mL of water, then add a solution of sodium hydroxide (1 in 50) until a slight precipitate is produced. Add 5 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and titrate with 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS (indicator: 0.04 g of eriochrome black T-sodium chloride indicator).

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS  
= 4.069 mg of ZnO

**Containers and storage** Containers—Tight containers.

## Zinc Sulfate

硫酸亜鉛

ZnSO<sub>4</sub>·7H<sub>2</sub>O: 287.56

Zinc Sulfate contains not less than 99.0% and not more than 102.0% of ZnSO<sub>4</sub>·7H<sub>2</sub>O.

**Description** Zinc Sulfate occurs as colorless crystals or a white, crystalline powder. It is odorless, and has an astringent, characteristic taste.

It is very soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

The pH of a solution of Zinc Sulfate (1 in 20) is between 3.5 and 6.0.

It effloresces in dry air.

**Identification** A solution of Zinc Sulfate (1 in 20) responds to the Qualitative Tests for zinc salt and for sulfate.

**Purity (1) Acid**—Dissolve 0.25 g of Zinc Sulfate in 5 mL of water, and add 1 drop of methyl orange TS: no red color develops.

(2) Heavy metals—Dissolve 1.0 g of Zinc Sulfate in 10 mL of water contained in a Nessler tube. Add 20 mL of potassium cyanide TS, and mix well. Add 2 drops of sodium sulfide TS, and allow the mixture to stand for 5 minutes. Observe vertically against a white background, the color of the solution is not more intense than the following control solution.

Control solution: To 1.0 mL of Standard Lead Solution add 10 mL of water and 20 mL of potassium cyanide TS, and mix well. Add 2 drops of sodium sulfide TS (not more than 10 ppm).

(3) Alkali earth metals and alkali metals—Dissolve 2.0 g of Zinc Sulfate in 150 mL of water, add a suitable amount of ammonium sulfide TS to complete the precipitation, and add water to make exactly 200 mL. Shake well, and filter through a dry filter paper. Discard the first 20 mL of the filtrate, take exactly 100 mL of the subsequent filtrate, evaporate to dryness, and ignite as directed under the Residue on Ignition: the mass of the residue is not more than 5.0 mg.

(4) Arsenic—Prepare the test solution with 1.0 g of Zinc Sulfate according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

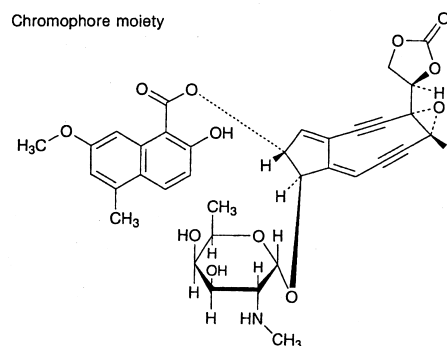
**Assay** Weigh accurately about 0.3 g of Zinc Sulfate, and dissolve in water to make exactly 100 mL. Measure exactly 25 mL of this solution, add 100 mL of water and 2 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and titrate with 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS (indicator: 0.04 g of eriochrome black T-sodium chloride indicator).

Each mL of 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS  
= 2.8756 mg of ZnSO<sub>4</sub>·7H<sub>2</sub>O

**Containers and storage** Containers—Tight containers.

## Zinostatin Stimalamer

ジノスタチン スチマラマー



(4*S*,6*R*,11*R*,12*R*)-11-[ $\alpha$ -D-2,6-Dideoxy-2-(methylamino)-galactopyranosyloxy]-4-[(4*R*)-2-oxo-1,3-dioxolan-4-yl]-