Each mL of 0.1 mol/L zinc VS
= 37.224 mg of $C_{10}H_{14}N_2Na_2O_8.2H_2O$

Containers and storage Containers—Well-closed containers.

Ephedra Herb

Ephdrae Herba

マオウ

Ephedra Herb is the terrestrial stem of *Ephedra sinica* Stapf, *Ephedra intermedia* Schrenk et C.A. Meyer or *Ephedra equisetina* Bunge (*Ephedraceae*).

Ephedra Herb, when dried, contains not less than 0.7% of total alkaloids [as ephedrine ($C_{10}H_{15}NO$: 165.23) and pseudoephedrine ($C_{10}H_{15}NO$: 165.23)].

Description Thin cylindrical or ellipsoidal cylinder, 0.1 - 0.2 cm in diameter; 3 - 5 cm in length of internode; light green to yellow-green; numerous parallel vertical furrows on the surface; scaly leaves at the node portion; leaves, 0.2 - 0.4 cm in length, light brown to brown in color, usually being opposite at every node, adhering at the base to form a tubular sheath around the stem. Under a magnifying glass, the transverse section of the stem appears as circle and ellipse, the outer portion grayish green to yellow-green in color, and the center filled with a red-purple substance or hollow. When fractured at internode, the outer part is fibrous and easily split vertically. Odor, slight; taste, astringent and slightly bitter, giving a slight sensation of numbness on the tongue.

Identification To about 0.5 g of pulverized Ephedra Herb add 10 mL of methanol, shake for 2 minutes, filter, and use the filter, and use the filtrate as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (7:2:1) to a distance of abour 10 cm, and air- day the plate. Spray evenly 2% ninhydrin-ethanol TS, and heat the plate at 105°C for 5 minutes: a rep-purple spot appears near *Rf* 0.35.

Purity **(1)** Woody stem—The amount of the woody stems contained in Ephedra Herb does not exceed 5.0%.

(2) Foreign matter—Ephedra Herb does not contain stems of *Equisetaceae* or *Gramineae* plants, or any other foreign matter.

Total ash Not more than 11.0%.

Acid-insoluble ash Not more than 2.0%.

Assay Weigh accurately about 0.5 g of medium powder of Ephedra Herb, previously dried in a desiccator (silica gel) for 24 hours, in a glass-stoppered centrifuge tube, add 20 mL of diluted methanol (1 in 2), shake for 30 minutes, centrifuge, and separate the supernatant liquid. Repeat this procedure twice with the residue using 20-mL portion of diluted methanol (1 in 2). Combine all the extracts, add diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.05 g of ephedrine hydrochloride for assay, previously dried at 105°C for 3 hours, and dissolve in diluted methanol (1 in 2) to make exactly 20 mL. Pipet 2 mL of the solution, add diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the standard solution. Pipet 10 μL each of the sample solution and the standard solution, and perform the test as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas, A_{TE} and A_{TP}, of ephedrine and pseudoephedrine (the relative retention time to ephedrine is about 0.9) in the sample solution, and the peak area, A_S, of ephedrine in the standard solution.

Amount (mg) of total alkaloids (ephedrine and pseudoephedrine)
= amount (mg) of ephedrine hydrochloride for assay
$\times \frac{A_{TE} + A_{TP}}{A_S} \times \frac{1}{10} \times 0.819$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 210 nm).

Column: A stainless steel column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 to 10 μm in particle diameter).

Column temperature: A constant temperature of about 45°C.

Mobile phase: A mixture of a solution of sodium lauryl sulfate (1 in 128), acetonitrile and phosphoric acid (640: 360:1).

Flow rate: Adjust the flow rate so that the retention time of ephedrine is about 14 minutes.

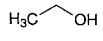
Selection of column: Dissolve 1 mg of ephedrine hydrochloride for assay and 4 mg of Atropine Sulfate in diluted methanol (1 in 2) to make 100 mL. Perform the test with 10 μL of this solution under the above operating conditions. Use a column giving elution of ephedrine and atropine in this order, clearly dividing each peak.

System repeatability: Repeat the test 6 times with the standard solution under the above operating conditions: the relative standard deviation of the peak area of ephedrine is not more than 1.5%.

Ethanol

Alcohol

エタノール



C_2H_6O: 46.07
Ethanol [*64-17-5*]

Ethanol contains not less than 95.1 vol% and not more than 95.6 vol% (by specific gravity) of C_2H_6O at 15°C.

Description Ethanol is a clear, colorless liquid. It has a characteristic odor and a burning taste.

It is miscible with water and with diethyl ether.

It is flammable and burns with a light blue flame on igni-

tion.

It is volatile.

Identification (1) Mix 1 mL of Ethanol with 2 mL of iodine TS and sodium hydroxide TS: a light yellow precipitate is produced.

(2) Heat 1 mL of Ethanol with 1 mL of acetic acid (100) and 3 drops of sulfuric acid: the odor of ethyl acetate is perceptible.

Specific gravity d_{15}^{15}: 0.814 - 0.816

Purity (1) Clarity of solution—Mix 10 mL of Ethanol with 30 mL of water, and allow to stand for 30 minutes between 5°C and 10°C: the mixture remains clear.

(2) Acid or alkali—Add 20 mL of freshly boiled and cooled water and 3 drops of phenolphthalein TS to 20 mL of Ethanol: no color develops. Add 0.10 mL of 0.1 mol/L sodium hydroxide VS to this solution: a red color develops.

(3) Chloride—Add 2 drops of dilute nitric acid and 2 drops of silver nitrate TS to 10 mL of Ethanol, and allow to stand for 5 minutes: the solution remains unchanged.

(4) Heavy metals—Proceed with 30 mL of Ethanol according to Method 1, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 1.2 ppm).

(5) Fusel oil constituents—Mix 10 mL of Ethanol with 5 mL of water and 1 mL of glycerin, and drop 0.3 mL of this mixture on odorless filter paper. Allow the mixture to volatilize at an ordinary temperature: no foreign odor remains. Carefully superimpose 5 mL of Ethanol on 5 mL of sulfuric acid in a test tube: no red color develops at the zone of contact.

(6) Aldehyde and other foreign reducing substances—To 10 mL of Ethanol at 15°C add 0.30 mL of 0.02 mol/L potassium permanganate VS, and allow to stand at 15°C for 20 minutes: the red color of the solution remains. Add 5 mL of sodium hydroxide TS to 10 mL of ethanol (95), and allow to stand for 5 minutes: no yellow color develops.

(7) Volatile impurities—Ethanol meets the requirements of the test.

(8) Residue on evaporation—Evaporate 40 mL of Ethanol, exactly measured, in a tared dish on a water bath, and dry for 1 hour at 105°C: the mass of the residue does not exceed 1.0 mg.

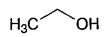
Containers and storage Containers—Tight containers.

Storage—Light-resistant, and remote from fire.

Dehydrated Ethanol

Dehydrated Alcohol

無水エタノール



C_2H_6O: 46.07

Ethanol [*64-17-5*]

Dehydrated Ethanol contains not less than 99.5 vol% (by specific gravity) of C_2H_6O at 15°C.

Description Dehydrated Ethanol is a clear, colorless liquid. It has a characteristic odor and a burning taste.

It is miscible with water and with diethyl ether.

It is flammable and burns with a light blue flame on ignition.

It is volatile.

Boiling point: 78 - 79°C

Identification (1) Mix 1 mL of Dehydrated Ethanol with 2 mL of iodine TS and 1 mL of sodium hydroxide TS: a light yellow precipitate is produced.

(2) Heat 1 mL of Dehydrated Ethanol with 1 mL of acetic acid (100) and 3 drops of sulfuric acid: the odor of ethyl acetate is perceptible.

Specific gravity d_{15}^{15}: not more than 0.797.

Purity (1) Clarity of solution—Mix 10 mL of Dehydrated Ethanol with 30 mL of water, and allow to stand for 30 minutes between 5°C and 10°C: the mixture remains clear.

(2) Acid or alkali—Add 20 mL of freshly boiled and cooled water and 3 drops of phenolphthalein TS to 20 mL of Dehydrated Ethanol: no color develops. Add 0.10 mL of 0.1 mol/L sodium hydroxide VS to this solution: a red color develops.

(3) Chloride—Add 2 drops of dilute nitric acid and 2 drops of silver nitrate TS to 10 mL of Dehydrated Ethanol, and allow to stand for 5 minutes: the solution remains unchanged.

(4) Heavy metals—Proceed with 30 mL of Dehydrated Ethanol according to Method 1, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 1.2 ppm).

(5) Fusel oil constituents—Mix 10 mL of Dehydrated Ethanol with 5 mL of water and 1 mL of glycerin, and drop 0.3 mL of this mixture on odorless filter paper. Allow the mixture to volatilize at an ordinary temperature: no foreign odor remains. Carefully superimpose 5 mL of Dehydrated Ethanol on 5 mL of sulfuric acid in a test tube: no red color develops at the zone of contact.

(6) Aldehyde and other foreign reducing substances—To 10 mL of Dehydrated Ethanol at 15°C add 0.30 mL of 0.02 mol/L potassium permanganate VS, and allow to stand at 15°C for 20 minutes: the red color of the solution remains. Add 5 mL of sodium hydroxide TS to 10 mL of Dehydrated Ethanol, and allow to stand for 5 minutes: no yellow color develops.

(7) Volatile impurities—Dehydrated Ethanol meets the requirements of the test.

(8) Residue on evaporation—Evaporate 40 mL of Dehydrated Ethanol, exactly measured, in a tared dish on a water bath, and dry for 1 hour at 105°C: the mass of the residue does not exceed 1.0 mg.

Containers and storage Containers—Tight containers.

Storage—Light-resistant, and remote from fire.