

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

Containers and storage Containers—Well-closed containers.

Ephedra Herb

Ephedrae 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 filtrate, and use the filtrate as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10 μ L 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 about 10 cm, and air-dry the plate. Spray evenly 2% ninhydrin-ethanol TS, and heat the plate at 105°C for 5 minutes: a red-purple spot appears near *R_f* 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 μ L 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)

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

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 octadecylsilylated silica gel for liquid chromatography (5 to 10 μ m 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.

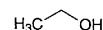
Selection of column: Dissolve 1 mg of ephedrine hydrochloride for assay and 4 mg of Atropine Sulfate in diluted methanol (1 in 2) to make 100 mL. Perform the test with 10 μ L of this solution under the above operating conditions. Use a column giving elution of ephedrine and atropine in this order, clearly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