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Ipecac Oral Solution

» Ipecac Oral Solution yields, from each 100 mL, not less than 123 mg and not more than 157 mg of the total ether-soluble alkaloids of ipecac. The content of emetine ($C_{29}H_{40}N_2O_4$) and cephaeline ($C_{28}H_{38}N_2O_4$) together is not less than 90.0 percent of the amount of the total ether-soluble alkaloids. The content of cephaeline varies from an amount equal to, to an amount not more than 2.5 times, the content of emetine.

Powdered Ipecac	70 g
Glycerin	100 mL
Syrup, a sufficient quantity, to make	1000 mL

Exhaust the powdered Ipecac by percolation, using a mixture of 3 volumes of alcohol and 1 volume of water as the menstruum, macerating for 72 hours, and percolating slowly. Reduce the entire percolate to a volume of 70 mL by evaporation at a temperature not exceeding 60° and preferably in vacuum, and add 140 mL of water. Allow the mixture to stand overnight, filter, and wash the residue on the filter with water. Evaporate the filtrate and washings to 40 mL, and to this add 2.5 mL of hydrochloric acid and 20 mL of alcohol, mix, and filter. Wash the filter with a mixture of 30 volumes of alcohol, 3.5 volumes of hydrochloric acid, and 66.5 volumes of water, using a volume sufficient to produce 70 mL of the filtrate. Add 100 mL of Glycerin and enough Syrup to make the product measure 1000 mL, and mix.

Packaging and storage—Preserve in tight containers, preferably at a temperature not exceeding 25°. Containers intended for sale to the public without prescription contain not more than 30 mL of Oral Solution.

USP REFERENCE STANDARDS (11)—

USP Emetine Hydrochloride RS

MICROBIAL ENUMERATION TESTS (61) and **TESTS FOR SPECIFIED MICROORGANISMS (62)**—It meets the requirements of the tests for absence of *Escherichia coli*.

ALCOHOL DETERMINATION (611): between 1.0% and 2.5% of C_2H_5OH .

Assay for total ether-soluble alkaloids—[NOTE—It is important that the ether used in this assay shall have been shown by test to be free from peroxides within 24 hours prior to use.] Transfer about 50 mL, accurately measured, of Oral Solution to a liquid-liquid automatic extractor, add water, if necessary, to reduce the viscosity, render the liquid distinctly alkaline with ammonium hydroxide, and extract with ether for at least 4 hours or until the extraction is complete. Use a water bath to boil the ether. Frequently disconnect the extractor from the condenser, and agitate the lower layer by raising and lowering the center tube or by other suitable manipulation. At the conclusion of the extraction period, transfer the ether extract to a separator, and rinse the extraction flask with 2 or more small volumes of ether, adding the rinsings to the separator. Complete the assay as directed in the *Assay for total ether-soluble alkaloids* under [Ipecac](#), beginning with “Extract the alkaloids from the ether.”

Assay for emetine and cephaeline—

Standard preparation, Phosphate buffer, and Citric acid buffer—Prepare as directed in the *Assay for emetine and cephaeline* under [Ipecac](#).

Assay preparation—Pipet 10 mL of water into a 25-mL volumetric flask. With the aid of a 20-mL pipet, add Oral Solution to volume, taking care to prevent contact of the Oral Solution with the neck of the flask above the graduation line. Insert the stopper, and mix.

Chromatographic columns—Pack a pledget of fine glass wool in the base of a chromatographic tube (25-mm × 200-mm test tube to which is fused a 5-cm length of 7-mm tubing) with the aid of a tamping rod having a disk with a diameter about 1 mm less than that of the tube. To prepare *Column I*, transfer 4.0 mL of the *Assay preparation* to a 150-mL beaker, add about 1 g of sodium bicarbonate, and mix. Then proceed as directed for *Chromatographic columns* in the *Assay for emetine and cephaeline* under [Ipecac](#), beginning with “add 6 g of purified siliceous earth,” and prepare *Columns II, III, and IV* as directed therein.

Procedure—Proceed as directed for *Procedure* in the *Assay for emetine and cephaeline* under [Ipecac](#).

Calculate the quantity, in mg, of emetine in each 100 mL of Oral Solution taken by the formula:

$$2.08C(A_{283} - A_{350})_U / (A_{283} - A_{350})_S$$

in which the parenthetic expressions are the differences in the absorbances of the solution of emetine from the *Assay preparation* (U) and the *Standard preparation* (S), respectively, at the wavelengths indicated by the subscripts, and C is as defined in the *Procedure*.

Calculate the quantity, in mg, of cephaeline in each 100 mL of Oral Solution taken by the formula:

$$0.971(2.08C)(A_{283} - A_{350})_U / (A_{283} - A_{350})_S$$

in which 0.971 is the ratio of the molecular weight of cephaeline to that of emetine, the parenthetic expressions are the differences in the absorbances of the solution of cephaeline from the *Assay preparation* (U) and the *Standard preparation* (S), respectively, at the wavelengths indicated by the subscripts, and C is as defined in the *Procedure*.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
IPECAC ORAL SOLUTION	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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