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Belladonna Tincture

» Belladonna Tincture yields, from each 100 mL, not less than 27 mg and not more than 33 mg of the alkaloids of belladonna leaf.

Belladonna Leaf, in moderately coarse powder	100 g
To make about	1000 mL

Prepare a tincture by *Process P* as modified for assayed *Tinctures* (see <u>Pharmaceutical Dosage Forms (1151)</u>), using a mixture of 3 volumes of alcohol and 1 volume of water as the menstruum. Finally adjust the Tincture to contain, in each 100 mL, 30 mg of the alkaloids of belladonna leaf.

Packaging and storage—Preserve in tight, light-resistant containers, and avoid exposure to direct sunlight and to excessive heat.

USP REFERENCE STANDARDS (11)

USP Atropine Sulfate RS

USP Homatropine Hydrobromide RS

USP Scopolamine Hydrobromide RS

ALCOHOL DETERMINATION, *Method II* (611): between 65.0% and 70.0% of C₂H₅OH, determined by the gas-liquid chromatographic procedure, acetone being used as the internal standard.

Assay-

pH 9.5 Phosphate buffer, Internal standard solution, Standard preparation, Extraction blank, Standard curve, Chromatographic system, and System suitability—Proceed as directed in the Assay under <u>Belladonna Extract</u>.

Assay preparation—Proceed with Tincture as directed in the Assay under <u>Belladonna Leaf</u>, but pipet 2 mL of Tincture (in place of "10 mL of this solution") into a 60-mL separator containing 10 mL of dilute sulfuric acid (1 in 350).

Procedure—Proceed as directed in the *Assay* under <u>Belladonna Leaf</u>. Record from the *Standard curve* the quantities, in mg, of atropine and scopolamine in the specimen. Add the quantity, in mg, of atropine and scopolamine, and multiply by 50 to obtain the weight, in mg, of alkaloids per 100 mL.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BELLADONNA TINCTURE	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

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