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Belladonna Extract Tablets

» Belladonna Extract Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of the alkaloids of belladonna leaf.

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11)-

USP Atropine Sulfate RS

USP Homatropine Hydrobromide RS

USP Scopolamine Hydrobromide RS

Identification—Macerate a quantity of powdered Tablets, equivalent to about 5 mg of the alkaloids of belladonna extract, with 20 mL of water, and transfer to a separator. Render the solution alkaline with 6 N ammonium hydroxide, and extract the alkaloids with 50 mL of chloroform. Filter the chloroform layer, divide it into two equal portions, and evaporate to dryness: the residue responds to the following tests.

- **A:** To one portion of the dry residue add 2 drops of nitric acid, evaporate on a steam bath to dryness, and add a few drops of alcoholic potassium hydroxide TS: a violet color is produced.
- **B:** Dissolve the other portion of the residue in 1 mL of dilute hydrochloric acid (1 in 120), and add gold chloride TS, dropwise with shaking, until a definite precipitate separates. Slowly heat until the precipitate dissolves, and allow the solution to cool: a lusterless precipitate is produced.

DISINTEGRATION (701): 30 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

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—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 600 µg of atropine and scopolamine, to a 60-mL separator, add 10.0 mL of dilute sulfuric acid (1 in 350), and sonicate to dissolve as much as possible of the specimen. Proceed as directed for Assay preparation in the Assay under <u>Belladonna Leaf</u>, beginning with "add 1.0 mL of <u>Internal standard solution."</u>

Procedure—Proceed as directed for <u>Procedure</u> in the <u>Assay</u> under <u>Belladonna Extract</u>. Record from the <u>Standard curves</u> the quantities, in mg, of atropine and scopolamine in the weight of specimen taken.

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

Topic/Question	Contact	Expert Committee
BELLADONNA EXTRACT TABLETS	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

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