Atropa belladonna Leaf

Proposed For Development Version 0.1

Atropa belladonna Leaf

DEFINITION
The article consists of the dried leaf of Atropa belladonna L. (Family Solanaceae). It meets the Acceptance criteria under the Assay [to come].

SYNONYMS
Atropa borealis Kreyer ex Pascher
Atropa cordata Pascher
Atropa digitaloides Pascher
Atropa lethalis Salisb.
Atropa lutescens Jacquem. ex C.B. Clarke
Atropa mediterranea Kreyer ex Pascher
Belladonna baccifera Lam.
Belladonna trichotoma Scop.
Boberella belladonna (L.) E.H.L. Krause

POTENTIAL CONFOUNDING MATERIALS
Althaea officinalis L.
Arctium lappa L.
Hyocyamus scopolia L.
Inula helenium L.
Medicago sativa L.
Scopolia carniolica Jacq.
Scopolia japonica Maxim.

SELECTED COMMON NAMES
English: Belladonna, deadly nightshade, divale, diwale, banewort, devil’s berries, naughty man’s cherries, death cherries, beautiful death, devil’s herb, great morel, dwaberry
French: Belladone, morelle furieuse
German: Tollkirsche
Portuguese: Beladama
Spanish: Belladona
CONSTITUENTS OF INTEREST

Tropane alkaloids: atropine, hyoscyamide, and scopolamine

IDENTIFICATION

• A. Botanical Characteristics

Macroscopic: Usually partly matted together, crumpled or broken leaves, together with some smaller stems and a number of flowers and fruits. The leaves are thin and brittle, mostly light-green to moderate olive-green. The lamina is mostly from 5 to 25 cm in length and from 4 to 12 cm in width and possesses an ovate-lanceolate to broadly ovate outline, an acute to acuminate apex, an entire margin, an acute to somewhat decurrent base, and slightly hairy surface, the hairs being more abundant along the veins; when broken transversely, it shows numerous light-colored dots (crystal cells) visible with a lens. The petiole is slender and usually up to 4 cm in length. The flowers possess a campanulate corolla with five small, reflexed lobes, purplish to yellowish-purple, becoming faded to brown or dusky-yellow or yellow, a green, 5-lobed calyx, five epipetalous stamens, and a superior, bilocular ovary with numerous ovules. The fruit is subglobose, dark yellow to yellowish-brown to dusky-red or black, up to about 12 mm in width and sometimes subtended by the persistent calyx and containing numerous flattened, somewhat reniform seeds, the latter up to about 2 mm in width. The stems are more or less flattened and hollow, and finely hairy when young.

Microscopic: The epidermis of the lamina possesses wavy anticlinal walls and a distinctly striated cuticle. Stomata are more numerous in the lower epidermis and are surrounded by three or four neighboring cells, one of which is smaller than the others. The nonglandular hairs are uniseriate and up to 6-celled. Short, club-shaped glandular hairs with a 1-celled stalk and multicellular head, and long glandular hairs with a uniseriate stalk and unicellular head occur on both epidermises. The mesophyll consists of a single layer of palisade parenchyma beneath which occurs spongy parenchyma, the latter with scattered cells filled with microcrystals. The midrib contains an arc of bicolateral bundles, collenchyma beneath upper epidermis, and scattered parenchyma cells with microcrystals.

• B. Thin-Layer Chromatography

CALL FOR SUBMISSION OF VALIDATED INFORMATION

Additional information including validation data will be required to complete the development of the Identification. For requirements, please see under “Identification” and related sections of the guidelines document “Monographs in the Herbal Medicines Compendium” at http://hmc.usp.org/about/general-noticesguidelines.

Interested parties are encouraged to submit their proposals to complete the monograph.

ASSAY

• Content of Constituents of Interest

CALL FOR SUBMISSION OF VALIDATED INFORMATION

Additional information including validation data will be required to complete the development of the Assay. For requirements, please see under “Composition” and related sections of the guidelines document “Monographs in the Herbal Medicines Compendium” at http://hmc.usp.org/about/general-noticesguidelines.
Interested parties are encouraged to submit their proposals to complete the monograph.

CONTAMINANTS

• **Elemental Impurities—Procedures <233>**
  
  **Acceptance criteria**
  
  **Arsenic:** NMT 2.0 µg/g  
  **Cadmium:** NMT 1.0 µg/g  
  **Lead:** NMT 5.0 µg/g  
  **Mercury:** NMT 0.2 µg/g

• **Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>:** Meets the requirements

• **Microbial Enumeration Tests <61>:** The total aerobic bacterial count does not exceed $10^5$ cfu/g, the total combined molds and yeasts count does not exceed $10^3$ cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed $10^3$ cfu/g.

• **Tests for Specified Microorganisms <62>:** Meets the requirements of the tests for the absence of Salmonella species and Escherichia coli

SPECIFIC TESTS

• **Articles of Botanical Origin, Foreign Organic Matter <561>:** NMT 3.0%

• **Articles of Botanical Origin, Total Ash <561>:** NMT 16%

• **Articles of Botanical Origin, Acid-Insoluble Ash <561>:** NMT 3%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, protected from light and moisture, and store at room temperature.

• **Labeling:** The label states the Latin binomial and the part(s) of the plant contained in the article.

• **USP Reference Standards <11>** [1]
  
  USP Atropine Sulfate RS [2]  
  USP Atropa belladonna Leaf Dry Extract RS  
  USP Hyoscyamine Sulfate RS [3]  
  USP Scopolamine Hydrobromide RS [4]

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