Official Monographs for NF 36

Acacia

DEFINITION
Acacia is the dried gummy exudate from the stems and branches of *Acacia senegal* (L.) Willd. or of other related African species of *Acacia* (Fam. Leguminosae).

IDENTIFICATION
- **A.**
  Analysis: To 10 mL of a cold solution (1 in 50) add 0.2 mL of diluted lead subacetate TS.
  Acceptance criteria: A flocculent, or curdy, white precipitate is formed immediately.

IMPURITIES
- **Arsenic,** *Method II* ⟨**211**⟩**:** NMT 3 ppm
- **Lead** ⟨**251**⟩**:** NMT 10 ppm

Delete the following:

- **Heavy Metals,** *Method II* ⟨**231**⟩**:** NMT 40 ppm (Official 1-Jan-2018)

SPECIFIC TESTS
- **Botanic Characteristics**
  Acacia: Spheroidal tears up to 32 mm in diameter or in angular fragments of white to yellowish white color. It is translucent or somewhat opaque from the presence of numerous minute fissures; very brittle, the fractured surface glassy and occasionally iridescent. It is almost odorless and produces a mucilaginous sensation on the tongue.
  Flake Acacia: White to yellowish white, thin flakes, appearing under the microscope as colorless, striated fragments
  Powdered Acacia: White to yellowish white, angular microscopic fragments with only traces of starch or vegetable tissues present
  Granular Acacia: White to pale yellowish white, fine granules. Under the microscope it appears as colorless, glassy, irregularly angular fragments up to 100 µm in thickness, some of which exhibit parallel linear streaks.
  Spray-dried Acacia: White to off-white compacted microscopic fragments or whole spheres
- **Microbial Enumeration Tests** ⟨**61**⟩ and **Tests for Specified Microorganisms** ⟨**62**⟩**:** Meets the requirements of the tests for absence of *Salmonella* species
- **Water Determination,** *Method III (Gravimetric)* ⟨**921**⟩
  Analysis: For unground Acacia, crush in a mortar until it passes through a No. 40 sieve, and mix the ground material before weighing the test specimen. Dry a sample at 105° for 5 h.
  Acceptance criteria: NMT 15.0% of its weight
- **Articles of Botanical Origin,** *Acid-Insoluble Ash* ⟨**561**⟩**:** NMT 0.5%
- **Articles of Botanical Origin,** *Total Ash* ⟨**561**⟩**:** NMT 4.0%
- **Insoluble Residue**
  Sample solution: Dissolve 5.0 g of powdered or finely ground Acacia in 100 mL of water. Add 10 mL of 3 N hydrochloric acid.
  Analysis: Boil the *Sample solution* gently for 15 min. Pass by suction, while hot, through a tared filtering crucible. Wash thoroughly with hot water, dry at 105° for 1 h, and weigh.
  Acceptance criteria: The weight of the residue thus obtained does not exceed 50 mg.
- **Starch or Dextrin**
  Sample solution: A solution (1 in 50)
  Analysis: Boil the *Sample solution* cool, and add iodine TS.
  Acceptance criteria: No bluish or reddish color is produced.
- **Solubility and Reaction**
  Sample: 1 g
  Analysis: Dissolve the *Sample* in 2 mL of water.
  Acceptance criteria: The resulting solution flows readily and is acid to litmus.
- **Tannin-Bearing Gums**
  Sample solution: A solution (1 in 50)
  Analysis: To 10 mL of the *Sample solution* add 0.1 mL of ferric chloride TS.
  Acceptance criteria: No blackish coloration or blackish precipitate is produced.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in tight containers.

Acacia Syrup

DEFINITION
Prepare Acacia Syrup as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Acacia, granular or powdered	100 g
Sodium Benzoate	1 g
Vanilla Tincture	5 mL
Sucrose	800 g
Purified Water, a sufficient quantity to make	1000 mL

Mix *Acacia*, *Sodium Benzoate*, and *Sucrose*. Add 425 mL of *Purified Water*, and mix. Heat the mixture on a steam bath until dissolved. When cool, remove the scum, add *Vanilla Tincture* and sufficient *Purified Water* to make the product measure 1000 mL, and strain, if necessary.

SPECIFIC TESTS
- **Microbial Enumeration Tests** ⟨**61**⟩ and **Tests for Specified Microorganisms** ⟨**62**⟩**:** Meets the requirements of the test for absence of *Salmonella* species

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Package in tight containers, and prevent exposure to excessive heat.
- **Labeling:** The label states the Latin binomial name and, following the official name, the part of the plant source from which the article was derived.