Mucuna pruriens Seed

Proposed For Development Version 0.1

Mucuna pruriens Seed

DEFINITION
The article consists of the dried seeds of Mucuna pruriens (L.) DC. (Family Fabaceae). It contains NLT 3.0% of levodopa on the dried basis.

SYNONYMS
Carpogon capitatus Roxb.
Carpogon niveus Roxb.
Carpopogon pruriens (L.) Roxb.
Dolichos pruriens L.
Marcanthes cochinchinensis Lour.
Mucuna axillaris Baker
Mucuna bernieriana Bail.
Mucuna cochinchenensis (Lour.) A. Chev.
Mucuna esquirolii H. Lev.
Mucuna luzoniensis Merr.
Mucuna lyonii Merr.
Mucuna minima Haines
Mucuna nivea (Roxb.) DC.
Mucuna prurita Wight
Mucuna sericophylla Perkins
Mucuna velutina Hassk.
Negretia mitis Blanco
Stizolobium capitatum (Roxb.) Kuntze
Stizolobium cochinchenensis (Lour.) Burk
Stizolobium niveum (Roxb.) Kuntze
Stizolobium pruritum (Wight) Piper
Stizolobium velutinum (Hassk.) Piper & Tracy

POTENTIAL CONFOUNGING MATERIALS
None known

SELECTED COMMON NAMES
Bengali: Akolchi
English: Velvet bean, Mucuna, Sea bean, Nescafe
Hindi: Kiwachi
Malayalam: Naicorna
Marathi: खाज-कुइरी Khaj-kuiri

CONSTITUENTS OF INTEREST
Amino acid: Levodopa
Alkaloids: Mucunine, mucunadine, pruriendine, and prurieninine

IDENTIFICATION
• A. BOTANICAL CHARACTERISTICS
Macroscopic: Ovoid, slightly compressed, with a persistent oblong, funicular hilum, dark brown with spots; usually 1.2-1.8 cm long, 0.8-1.2 cm wide, hard, smooth to touch, not easily breakable

Microscopic: Thin seed coat and two hard cotyledons; outer testa consists of single-layered palisade-like cells; inner testa composed of 2 or 3 layers, outer layer of tangentially elongated, ovoid, thin-walled cells, inner 1 or 2 layers of dumb-bell or beaker-shaped, thick-walled cells; tegmen composed of a wide zone of oval to elliptical, somewhat compressed, thin-walled, parenchymatous cells; some cells contain starch grains; cotyledons composed of polygonal, angular, thin-walled, compactly arranged parenchymatous cells, containing aleurone and starch grains; starch grains small; simple, rounded to oval measuring 6–41 µm in diameter, but not over 45 µm in diameter; a few vascular bundles with vessels showing reticulate thickening or pitted present

B. Thin-Layer Chromatography

Standard solution A: 0.5 mg/mL of USP Levodopa RS in 30% phosphoric acid

Standard solution B: Sonicate an amount of USP Mucuna pruriens Seed Powder RS with 1/5 the total volume of 30% phosphoric acid for 5 min. Add 4/5 of the total volume of methanol and mix by vortex to prepare 20 mg/mL solution. Centrifuge and use the supernatant.

Sample solution: Mix 1 g of Mucuna pruriens Seed, finely powdered, with 10 mL of 30% phosphoric acid in a 50-mL centrifuge tube. Sonicate for 5 min, add 40 mL of methanol, and mix by vortex. Centrifuge and use the supernatant.

Chromatographic system
(See Chromatography <621>, Thin-Layer Chromatography.)

Adsorbent: Chromatographic silica gel F254, mixture with an average particle size of 5 µm

Application volume: 10 µL as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device

Developing solvent system: Butanol, alcohol, acetic acid, and water (60:32:12:8)

Developing distance: 8 cm

Derivatization reagent: 30 mg of ninhydrin into 10 mL of butanol and 0.3 mL of glacial acetic acid.

Analysis

Samples: Standard solution A, Standard solution B, and Sample solution

Apply the Samples as bands and dry in air. Develop in a saturated chamber (20 min with filter paper), remove the plate from the chamber, and dry in air. Treat the plate with the Derivatization reagent, heat at 100° for 5 min, and examine under white light.

System suitability: Under white light, the chromatogram of Standard solution B exhibits the most intense dark gray or black band with similar Rf and color as the levodopa band in the chromatogram of Standard solution A. Three to four dark pink bands appear below the levodopa band and one strong and two weak dark pink bands appear above the levodopa band.

Acceptance criteria: Under white light, the chromatogram of the Sample solution exhibits the most intense dark gray or black band in the middle of the chromatogram, corresponding in Rf to the levodopa band in Standard solution A. The Sample solution exhibits additional bands corresponding to similar bands in Standard solution B, in particular, two weak pink bands: one above and one below the levodopa band.

C. HPLC

Analysis: Proceed as directed in the test for Content of Levodopa.

Acceptance criteria: The Sample solution exhibits the most intense peak at a retention time corresponding to the peak due to levodopa in Standard solution A and Standard solution B.

ASSAY

Content of Levodopa

Solution A: 1.36 g of monobasic potassium phosphate in 900 mL of water and adjust with phosphoric acid to a pH of 2.5.

Solution B: Methanol

Mobile phase: A mixture of Solution A and Solution B (92:8)

Standard solution: 0.2 mg/mL of USP Levodopa RS prepared as follows: in a volumetric flask, dissolve the USP Levodopa RS in a volume of 30% phosphoric acid equivalent to 1/20 the flask’s nominal volume and dilute to volume with water.

System suitability solution: 25 mg/mL of USP Mucuna pruriens Seed Powder RS prepared as follows: Transfer a suitable amount of USP Mucuna pruriens Seed Powder RS to a centrifuge tube. Sonicate for 5 min in a volume of 9% phosphoric acid equivalent of about 1/20 of the final volume. Dilute with water to final volume, mix well and centrifuge. Before injection, pass through a polysulfone membrane filter of 0.45-µm or finer pore size.

Sample solution: Transfer about 2.5 g of Mucuna pruriens Seed, finely powdered and accurately weighed, into a 100-mL centrifuge tube, and add 25 mL of 9% phosphoric acid. Sonicate for 5 min, centrifuge at 3000 rpm for 5 min, and transfer the supernatant to a 100-mL volumetric flask. Repeat the extraction three more times by adding 20 mL of 9% phosphoric acid, and transferring the supernatant to the same 100-mL volumetric flask; dilute with 9% phosphoric acid to volume, and mix. Before injection, pass through a polysulfone membrane filter of 0.45-µm or finer pore size and discard the first portion of the filtrate.

Chromatographic system
(See Chromatography <621>, System Suitability.)

Detector: UV 280 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1 (similar to Merck kGaA Purospher Star RP-18)
Column temperature: 30°
Flow rate: 1.0 mL/min
Injection volume: 20 µL

System suitability

Samples: Standard solution and System suitability solution

Suitability requirements

- Resolution: NLT 1.5 between levodopa and the peak before it, System suitability solution
- Tailing factor: NMT 1.5 for the levodopa peak, Standard solution
- Relative standard deviation: NMT 2.0% for the levodopa peak in repeated injections, Standard solution

Analysis

Samples: Standard solution A and Sample solution

Using the chromatograms of Standard solution and the reference chromatogram provided with the lot of USP Mucuna pruriens Seed Powder RS being used, identify the retention times of the peaks corresponding to the peaks due to levodopa in the Sample solution.

Calculate the percentage of levodopa in the portion of Mucuna pruriens Seed taken:

Result = \( \frac{r_U}{r_S} \times C_S \times \frac{V}{W} \times 100 \)

- \( r_U \) = peak area of levodopa from the Sample solution
- \( r_S \) = peak area of levodopa from Standard solution
- \( C_S \) = concentration of the USP Levodopa RS in Standard solution (mg/mL)
- \( V \) = volume of the Sample solution (mL)
- \( W \) = weight of Mucuna pruriens Seed taken to prepare the Sample solution (mg)

Acceptance criteria: NLT 3.0% of levodopa on the dried basis

CONTAMINANTS

- **Elemental Impurities—Procedures <233>**
  - Acceptance criteria
    - Arsenic: NMT 2.0 µg/g
    - Cadmium: NMT 0.5 µg/g
    - Lead: NMT 5 µg/g
    - Mercury: NMT 0.2 µg/g

- **Articles of Botanical Origin <561>, Pesticide Residue Analysis**: Meets the requirements

- **Microbial Enumeration Tests <61>**: The total aerobic bacterial count does not exceed 105 cfu/g, the total combined molds and yeasts count does not exceed 103 cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed 103 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 <561>, Methods of Analysis, Foreign Organic Matter**: NMT 1.0%
- **Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1**: NLT 3.0%
- **Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2**: NLT 23.0%
- **Water Determination <921>, Method II**: NMT 8.0%

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>**
  - USP Levodopa RS
  - USP Mucuna pruriens Seed Powder RS

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