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Add the following:

▲Aloe Vera Leaf Dry Juice

DEFINITION

Aloe Vera Leaf Dry Juice consists of the dried juice obtained from either the inner leaf or the whole leaf of *Aloe vera* (L.) Burm.f. (Fam. Asphodelaceae), processed to contain NMT 0.05 µg/g of hydroxyanthracene-derived substances (aloins) on the single-strength juice basis. It contains NLT 0.03% of acemannan, calculated as aloeoverose¹ on the single-strength juice basis. It may contain added substances.

IDENTIFICATION

• A. ¹H NMR SPECTROSCOPY

Analysis: Proceed as directed in the *Content of Acemannans* test.

Acceptance criteria: The *Sample solution* exhibits characteristic hydrogen resonance fingerprint patterns at chemical shifts between 2.00 and 2.30 ppm that closely match those of [USP Aloeoverose RS](#). The fingerprint patterns comprise a group of maxima and/or shoulders corresponding to individual singlets of the methyl groups. NLT 3 main maxima are observed at 2.18 ± 0.01 , 2.15 ± 0.01 , and 2.11 ± 0.01 ppm, with the resonance at 2.11 ± 0.01 ppm exhibiting lower intensity. Additional peak maxima or shoulders may be observed in this region. The *Sample solution* also exhibits characteristic patterns for the anomeric protons of glucose (5.20 ppm for α-glucose and 4.60 ppm for β-glucose) and for malic acid (4.30 ppm). Aloe Vera Leaf Dry Juice labeled as containing juice derived from the whole leaf shows a resonance at 4.25 ppm corresponding to isocitric acid. Aloe Vera Leaf Dry Juice labeled as containing juice only from the inner leaf lacks patterns in the parts per million range corresponding to isocitric acid. Aloe Vera Leaf Dry Juice labeled to contain added substances shows resonances for the corresponding compounds.

COMPOSITION

• CONTENT OF ACEMANNANS

Solvent: Deuterium oxide (D₂O), containing 0.01 mg/mL of 4,4-dimethyl-4-silapentane-1-sulfonic acid (DSS)

Standard solution: In a centrifuge tube, dissolve about 5 mg each of [USP Aloeoverose RS](#), [USP Dextrose RS](#), and [USP Malic Acid RS](#) in 1.4 mL of the *Solvent*. Mix well with sonication for 15 min, centrifuge, and transfer 0.7 mL of the supernatant to a 5-mm NMR tube.

Sample solution: Accurately weigh about 10–20 mg of Aloe Vera Leaf Dry Juice and 5 mg of [USP Niacinamide RS](#) in a centrifuge tube, and dissolve in 0.7 mL of the *Solvent*. Sonicate for 15 min, shaking occasionally. Add an additional 0.7 mL of the *Solvent* and mix. Centrifuge and transfer 0.7 mL of the supernatant to a 5-mm NMR tube.

System suitability solution: In a 1-mL glass vial, dissolve 5 mg of [USP Niacinamide RS](#) in 0.7 mL of the *Solvent*. Transfer the solution to a 5-mm NMR tube.

Instrumental conditions

(See [Nuclear Magnetic Resonance Spectroscopy \(761\)](#), [Qualitative and Quantitative NMR Analysis](#), [Qualitative Applications](#).)

Mode: Proton (¹H) NMR

Magnetic field strength: NLT 7.05 tesla, corresponding to 300 MHz for ¹H frequency

Pulse sequence: Single pulse for proton

Pulse angle: 90°

Sweep width: 15 ppm

Temperature: 25°

Acquired data points: NLT 64,000

Relaxation delay: NLT 15 s

Number of scans: NLT 16

System suitability

Sample: *System suitability solution*

Acquire free induction decay (FID) and obtain the Fourier transform NMR spectrum. Set the DSS methyl resonance to 0.00 ppm. Prior to measuring the response intensity by integration, apply phase correction and baseline correction for the entire spectrum.

Suitability requirements

Chemical shift: The position of the center of the niacinamide peak pattern relative to that of the DSS methyl group is within 7.58 ± 0.05 ppm, measured in 5 scans.

Signal-to-noise ratio: NLT 150 for the maximum of the niacinamide peak pattern at 7.58 ppm

Analysis

Samples: *Standard solution* and *Sample solution*

Using the NMR spectrum of the *Standard solution* and the reference NMR spectrum provided with the lot of [USP Aloeverose RS](#) being used, identify the peak pattern between 2.00 and 2.30 ppm in the *Sample solution* that corresponds to acetyl groups of acemannan. Integrate the peak pattern in this area. Use the peak pattern centered at 7.58 ppm for niacinamide as the internal calibrant for quantitation.

Calculate the percentage of acemannan, as aloeverose, in the portion of Aloe Vera Leaf Dry Juice taken:

$$\text{Result} = F \times (W_N \times I_A) / (W_A \times I_N) \times (1/L) \times P$$

F = conversion factor for molecular weight and number of hydrogens for acetylated polysaccharide versus niacinamide, 0.766²

W_N = weight of the added niacinamide internal standard (mg)

I_A = integral of the acetyl methyl groups (a group of singlets in the 2.00–2.30 ppm range) corresponding to acemannans

W_A = weight of Aloe Vera Leaf Dry Juice taken to prepare the *Sample solution* (mg)

I_N = integral of the aromatic resonance of a methine hydrogen at 7.58 ppm

L = conversion factor of dry juice to single-strength liquid juice as indicated on the label

P = purity of niacinamide (%)

Acceptance criteria: NLT 0.03% on the single-strength juice basis

CONTAMINANTS

- [ARTICLES OF BOTANICAL ORIGIN \(561\)](#), [Limits of Elemental Impurities](#): Meets the requirements
- [ARTICLES OF BOTANICAL ORIGIN \(561\)](#), [Pesticide Residue Analysis](#): Meets the requirements
- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic bacterial count does not exceed 10³ cfu/g, and the total combined molds and yeasts count does not exceed 10² cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#), [Test Procedures](#), [Test for Absence of Salmonella Species](#) and [Test for Absence of Escherichia coli](#): Meets the requirements

SPECIFIC TESTS

- **LIMIT OF ANTHRONE GLYCOSIDES** (anthraquinone glycosides and hydroxyanthracene derivatives)

Solution A: 0.1% [glacial acetic acid](#) in [water](#)

Solution B: 0.1% [glacial acetic acid](#) in [acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
13	65	35
30	0	100
31	80	20
40	80	20

Solvent: [Methanol](#) and [water](#) (60:40)

Standard solution: 0.1 µg/mL of [USP Aloin A RS](#) and [USP Aloin B RS](#) in the *Solvent*

Sample solution: Transfer 0.1 g of Aloe Vera Leaf Dry Juice to a 15-mL centrifuge tube and add 1 mL of [water](#). Mix well to dissolve the water-soluble constituents. Add 1 mL of [ethanol](#) and 2 mL of saturated [sodium chloride](#) solution into the tube and mix well. Add 4 mL of a solution of [ethyl acetate](#) and [methanol](#) (90:10), cap the tube, and mix well for 60 s. Centrifuge the sample at 2000 rpm for 5 min. Transfer the top layer to a 15-mL centrifuge tube. Repeat the extraction, using 4 mL of a solution of [ethyl acetate](#) and [methanol](#) (90:10). Mix the sample well for 30 s and centrifuge at 2000 rpm for 5 min. Combine the top layers and, in a 50° water bath, evaporate to dryness with a stream of nitrogen. Add 0.5 mL of the *Solvent* to the dried sample residue and mix well. Pass the sample through a 0.2-µm PVDF filter.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 380 nm

Column: 4.6-mm × 25-cm; 4.0-µm packing [L1](#)