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Aloe

Change to read:

DEFINITION

Aloe is the dried latex of the leaves of *Aloe vera* (L.) Burm.f. (syn. *Aloe barbadensis* Mill.), known in commerce as aloe vera, Curaçao aloe, or Barbados aloe; or of the leaves of *Aloe ferox* Mill., or of hybrids of *Aloe ferox* Mill. with *Aloe africana* Mill. and *Aloe spicata* L.f., known in commerce as Cape aloe (Family ▲Asphodelaceae).▲ (USP 1-May-2023) Aloe vera contains NLT 16.0% of ▲aloin A[1]▲ (USP 1-May-2023) and Cape aloe and its hybrids contain NLT 6.0% of ▲aloin A,▲ (USP 1-May-2023) both calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample: 1 g, finely powdered

Analysis: In a 100-mL volumetric flask, mix the *Sample* with 25 mL of cold water. Shake the mixture occasionally for 2 h, filter, and wash the filter and residue with sufficient cold water until the filtrate measures 100 mL.

Acceptance criteria: The color of the filtrate, viewed in the bulb of a 100-mL volumetric flask, is dark orange with Curaçao aloe and greenish-yellow with Cape aloe. The filtrate darkens on standing. [NOTE—Reserve the filtrate for *Identification B*.]

• **B.**

Sample: 5 mL of the filtrate obtained in *Identification A*

Analysis: Add 2 mL of nitric acid to the *Sample*, and mix.

Acceptance criteria: The mixture exhibits a reddish-orange color with aloe vera and a reddish-brown color that changes rapidly to green with Cape aloe.

Change to read:

• **C.** ▲**HPTLC FOR ARTICLES OF BOTANICAL ORIGIN ⟨203⟩**▲ (USP 1-MAY-2023)

Standard solution: 1.0 mg/mL of ▲USP Aloin A RS▲ (USP 1-May-2023) in methanol

Sample solution: 0.5 g of finely powdered Aloe in 10 mL of methanol. Sonicate for 15 min, centrifuge or filter, and use the supernatant or the filtrate.

Chromatographic system

▲(See standard parameters as defined in *HPTLC for Articles of Botanical Origin ⟨203⟩*, *Table 1*.)▲ (USP 1-May-2023)

Application volume: 2 µL of the *Standard solution* and 5 µL of the *Sample solution*, as 8-mm bands ▲▲ (USP 1-May-2023)

Developing solvent system: Ethyl acetate, methanol, and water (100:17:13) ▲▲ (USP 1-May-2023)

Derivatization reagent: 10% potassium hydroxide solution in methanol. Prepare in an ice bath.

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples* as bands to a suitable HPTLC plate. Use a saturated chamber. Develop the chromatograms, dry in air, derivatize with *Derivatization reagent*, and heat at 110° for 5 min. Examine under white light and long-wave UV light.

Acceptance criteria

Under white light: The *Sample solution* exhibits a brown band due to ▲aloin A▲ (USP 1-May-2023) at about the middle of the chromatogram, corresponding in color and R_F to the band exhibited by the *Standard solution*. The *Sample solution* containing aloe vera exhibits an additional violet band due to 7-hydroxyaloin right below the ▲aloin A▲ (USP 1-May-2023) band. The *Sample solution* containing Cape aloe lacks the violet band due to 7-hydroxyaloin.

Under long-wave UV light: The *Sample solution* exhibits a yellow fluorescence band due to ▲aloin A,▲ (USP 1-May-2023) corresponding in color and R_F to the band exhibited by the *Standard solution*, as well as a light blue fluorescence band due to ▲aloesin▲ (USP 1-May-2023) in the lower-third of the chromatogram.

COMPOSITION

Change to read:

• **Content of ▲Aloin A▲** (USP 1-May-2023)

Mobile phase: A mixture of acetonitrile and water (3:7)

Standard solution: 0.1 mg/mL of ▲USP Aloin A RS▲ (USP 1-May-2023) in methanol and water (1:1)

Sample solution: Transfer about 0.1 g of aloe vera or 0.2 g of Cape aloe, finely powdered and accurately weighed, to a 100-mL volumetric flask and add about 75 mL of methanol. Sonicate for 30 min, cool to room temperature, adjust with methanol to volume, and mix. Before injection, pass through a PTFE membrane filter of 0.45-µm pore size, discarding the first few milliliters of the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 295 nm

Column: 4.6-mm × 25-cm; end-capped 5-µm packing L1

Column temperature: 43 ± 1°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates for the ▲aloin A▲ (USP 1-May-2023) peak

Tailing factor: NMT 2.0 for the ▲aloin A▲ (USP 1-May-2023) peak

Relative standard deviation: NMT 2.0% for the ▲aloin A▲ (USP 1-May-2023) peak in repeated injections

Analysis

Samples: *Standard solution* and *Sample solution*

[Note—The *Standard solution* and *Sample solution* are stable for 8 h at room temperature.]

Using the chromatogram of the *Standard solution*, identify the retention time of the peak corresponding to ▲aloin A▲ (USP 1-May-2023) in the *Sample solution*.

Calculate the percentage of ▲aloin A▲ (USP 1-May-2023) in the portion of Aloe taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times 100$$

r_U = peak area of ▲aloin A▲ (USP 1-May-2023) from the *Sample solution*

r_S = peak area of ▲aloin A▲ (USP 1-May-2023) from the *Standard solution*

C_S = concentration of ▲USP Aloin A RS▲ (USP 1-May-2023) in the *Standard solution* (mg/mL)

V = final volume of the *Sample solution* (mL)

W = weight of Aloe taken to prepare the *Sample solution* (mg)

Acceptance criteria: Aloe vera contains NLT 16.0% of ▲aloin A,▲ (USP 1-May-2023) and Cape aloe or its hybrids contain NLT 6.0% of ▲aloin A,▲ (USP 1-May-2023) both on the dried basis.

• **Water-Soluble Extractive**

Sample: 2 g of powdered Aloe

Analysis: Macerate the *Sample* in 70 mL of water in a suitable flask. Shake the mixture for 8 h at 30-min intervals and allow it to stand for 16 h without shaking. Filter, and wash the flask and residue with small portions of water, passing the washings through the filter until the filtrate is 100.0 mL. Evaporate a 50-mL aliquot of the filtrate in a tared dish on a steam bath to dryness, and dry at 110° to constant weight.

Acceptance criteria: The weight of water-soluble extractive is NLT 50% of the weight of Aloe taken.

CONTAMINANTS

• **Articles of Botanical Origin ⟨561⟩, *Pesticide Residue Analysis*:** Meets the requirements

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Sample: Use a powdered sample. If the Aloe is not powdered, crush it in a mortar until it passes through a no. 40 sieve, and mix the ground material before weighing the sample.

Analysis: Dry the *Sample* at 105° for 5 h.

Acceptance criteria: NMT 12.0%

• **Articles of Botanical Origin ⟨561⟩, *Methods of Analysis*, *Total Ash*:** NMT 4.0%

• **Alcohol-Insoluble Substances**

Sample: 1 g of powdered Aloe

Analysis: Add the *Sample* to 50 mL of alcohol in a flask. Heat the mixture to boiling, and maintain at incipient boiling for 15 min, replacing any loss due to evaporation. Remove from the heat and shake at intervals for 1 h. Pass through a small dried and tared filter paper or a dried and tared filtering crucible, and wash the residue on the filter with alcohol until the last washing is colorless. Dry the residue at 105° to constant weight.

Acceptance criteria: The weight of the residue is NMT 10.0% of the weight of Aloe taken.

• **Botanical Characteristics**

Curaçao aloe: Brownish-black, opaque masses. Its fractured surface is uneven, waxy, and somewhat resinous.

Cape aloe: Dusky to dark brown irregular masses, the surfaces of which are often covered with a yellowish powder. Its fracture is smooth and glassy.

Powdered Aloe: Yellow, yellowish brown to olive-brown in color. When mounted in olive oil, it appears as greenish-yellow to reddish-brown irregular fragments, the hues of which depend to some extent upon the thickness of the fragments.

ADDITIONAL REQUIREMENTS

Change to read:

• **USP Reference Standards** ⟨11⟩

▲ USP Aloin A RS▲ (USP 1-May-2023)

[1] Also known as aloin.

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

Topic/Question	Contact	Expert Committee
ALOE	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

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