USP Almotriptan Related Compound C RS
N-Methyl-2-{5-[(pyrrolidin-1-ylsulfonyl)methyl]-1*H*-indol-3-yl}ethanamine.
$C_{16}H_{23}N_3O_2S$ 321.44
USP Almotriptan Related Compound D RS
1-[({3-[2-(Dimethylamino)ethyl]indol-5-yl}methyl-)sulfonyl]pyrrolidine *N*-oxide.
$C_{17}H_{25}N_3O_3S$ 351.46

Aloe

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 *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 (Fam. Liliaceae). Aloe vera contains NLT 16.0% of aloin, and cape aloe and its hybrids contain NLT 6.0% of aloin, both calculated on the dried basis.

IDENTIFICATION
• **A.**
Sample: 1 g, finely powdered
Analysis: 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 to make the filtrate measure 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.

• **C. THIN-LAYER CHROMATOGRAPHY**
Standard solution: 1.0 mg/mL of USP Aloin RS 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 *Chromatography* ⟨621⟩, *General Procedures, Thin-Layer Chromatography.*)
Adsorbent: Chromatographic silica gel mixture with an average particle size of 5 µm (HPTLC plates)
Application volume: 2 µL of the *Standard solution* and 5 µL of the *Sample solution* as 8-mm bands
Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device.
Developing solvent system: Ethyl acetate, methanol, and water (100:17:13)
Developing distance: 6 cm
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 visible light and UV light at 365 nm.
Acceptance criteria: Under visible light, the *Sample solution* exhibits a brown band due to aloin 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 band. The *Sample solution* containing cape aloe lacks the violet band due to 7-hydroxyaloin. Under UV light at 365 nm, the *Sample solution* exhibits a yellow fluorescence band due to aloin, corresponding in color and R_F to the band exhibited by the *Standard solution*, and a light blue fluorescence band due to aloesine at about one-third of the chromatogram.

COMPOSITION
• **CONTENT OF ALOIN**
Mobile phase: A mixture of acetonitrile and water (3:7)
Standard solution: 0.1 mg/mL of USP Aloin RS 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 mL 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 peak
Tailing factor: NMT 2.0 for the aloin peak
Relative standard deviation: NMT 2.0% determined from the aloin 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 in the *Sample solution*.
Calculate the percentage of aloin 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 from the *Sample solution*
r_S = peak area of aloin from the *Standard solution*
C_S = concentration of USP Aloin RS 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, and cape aloe and its hybrids contain NLT 6.0% of aloin, 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 measures 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.