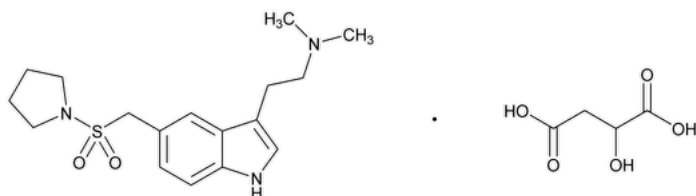


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Almotriptan Malate



$C_{17}H_{25}N_3O_2S \cdot C_4H_6O_5$ 469.55

Pyrrolidine, 1-[[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]sulfonyl]-, hydroxybutanedioate (1:1);

1-[[[3-[2-(Dimethylamino)ethyl]indol-5-yl]methyl]sulfonyl]pyrrolidine malate (1:1) CAS RN®: 181183-52-8; UNII: PJP312605E.

DEFINITION

Almotriptan Malate contains NLT 98.0% and NMT 102.0% of almotriptan malate ($C_{17}H_{25}N_3O_2S \cdot C_4H_6O_5$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 2.72 g/L of [monobasic potassium phosphate](#) in water. Adjust with [phosphoric acid](#) to a pH of 3.5.

Mobile phase: [Methanol](#) and *Buffer* (40:60)

System suitability solution: 0.14 mg/mL each of [USP Almotriptan Malate RS](#) and [USP Almotriptan Related Compound B RS](#) in *Mobile phase*.
 Sonication may be used to promote dissolution.

Standard solution: 0.14 mg/mL of [USP Almotriptan Malate RS](#) in *Mobile phase*. Sonication may be used to promote dissolution.

Sample solution: 0.14 mg/mL of Almotriptan Malate in *Mobile phase*. Sonication may be used to promote dissolution.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L10](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 2 times the retention time of almotriptan

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for almotriptan related compound B and almotriptan are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between almotriptan and almotriptan related compound B, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.85% for six injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of almotriptan malate ($C_{17}H_{25}N_3O_2S \cdot C_4H_6O_5$) in the portion of Almotriptan Malate taken:

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

r_U = peak response of almotriptan from the *Sample solution*

r_s = peak response of almotriptan from the *Standard solution*

C_s = concentration of [USP Almotriptan Malate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Almotriptan Malate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.10%

• **LIMIT OF ALMOTRIPTAN RELATED COMPOUND D AND ALMOTRIPTAN N-DIMER**

Run buffer: 23.5 g/L of [phosphoric acid](#) in [water](#). Adjust with [triethanolamine](#) to a pH of 3.0 and pass through a suitable filter of 0.45-µm pore size.

Diluent: [Methanol](#) and [water](#) (50:50)

Internal standard solution: 0.01 mg/mL of [4-hydroxy-4-phenylpiperidine](#) in *Diluent*

System suitability solution: 0.005 mg/mL each of [USP Almotriptan Related Compound B RS](#), [USP Almotriptan Related Compound D RS](#), and [USP Almotriptan Malate RS](#) in the *Internal standard solution*. Pass through a suitable filter of 0.45-µm pore size.

Standard stock solution: 0.5 mg/mL of [USP Almotriptan Malate RS](#) in *Diluent*

Standard solution: 0.005 mg/mL of [USP Almotriptan Malate RS](#) from the *Standard stock solution* in the *Internal standard solution*. Pass through a suitable filter of 0.45-µm pore size.

Sample solution: 2.5 mg/mL of Almotriptan Malate in the *Internal standard solution*. Sonication may be used to promote dissolution. Pass the solution through a suitable filter of 0.45-µm pore size.

Capillary rinsing procedure: Use separate *Run buffer* vials for the capillary rinse and sample analysis. Condition the capillary by rinsing with [water](#), [0.1 N sodium hydroxide](#), [water](#), and the *Run buffer* before each injection. [NOTE—It may be suitable to rinse with [water](#), [0.1 N sodium hydroxide](#), and [water](#) using a pressure of 20 psi for NLT 2 min each and then to rinse with the *Run buffer* using a pressure of 20 psi for NLT 5 min.]

Instrumental conditions

Mode: CE

Detector: UV 214 nm

Capillary, Capillary effective length, Capillary temperature, and Voltage: Use parameters described under A or B as indicated in [Table 1](#).

Table 1

Parameter	A	B
Capillary	75-µm × 48.5-cm; uncoated fused silica	75-µm × 60-cm; uncoated fused silica
Capillary effective length	40 cm	47 cm
Capillary temperature	15°	25°
Voltage	A voltage of 15.5 kV may be suitable.	A voltage of 15.0 kV may be suitable.

Injection sequence: 0.5 psi for 8 s for the *Sample solution*, followed by 0.5 psi for 1 s for the *Run buffer*

Run time: NLT 2.5 times the migration time of almotriptan

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 2](#) for the relative migration times.]

Suitability requirements

Resolution: NLT 2.0 between almotriptan related compound B and almotriptan; NLT 2.0 between almotriptan and almotriptan related compound D, *System suitability solution*

Relative standard deviation: NMT 5.0% for the ratio of the peak response of almotriptan to the peak response of the internal standard, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the corrected peak response:

$$\text{Result} = (r/m)$$

r = peak response

m = migration time of the peak (min)