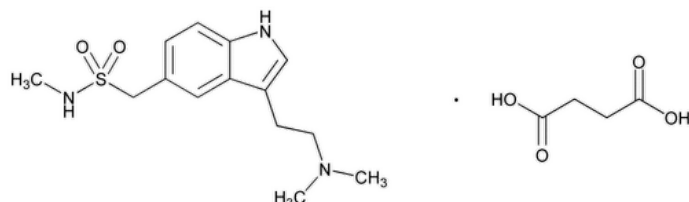


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Sumatriptan Succinate



$C_{14}H_{21}N_3O_2S \cdot C_4H_6O_4$ 413.49

1*H*-Indole-5-methanesulfonamide, 3-[2-(dimethylamino) ethyl]-*N*-methyl-, butanedioate (1:1);

3-[2-(Dimethylamino)ethyl]-*N*-methylindole-5- methanesulfonamide succinate (1:1) CAS RN[®]: 103628-48-4; UNII: J8BDZ68989.

DEFINITION

Sumatriptan Succinate contains NLT 98.0% and NMT 102.0% of sumatriptan succinate ($C_{14}H_{21}N_3O_2S \cdot C_4H_6O_4$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (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: Dissolve 1.7 mL of dibutylamine, 0.6 mL of phosphoric acid, and 3.9 g of sodium dihydrogen phosphate dihydrate in 750 mL of water. Adjust with a solution of 50% (w/v) sodium hydroxide to a pH of 6.5, and dilute with water to 1 L.

Diluent: Dissolve 2.97 g of monobasic sodium phosphate in 600 mL of water, adjust with a solution of 50% (w/v) sodium hydroxide to a pH of 6.5, dilute with water to 750 mL, and add 250 mL of acetonitrile.

Mobile phase: Acetonitrile and *Buffer* (200:800)

System suitability solution: 0.28 mg/mL of [USP Sumatriptan Succinate RS](#) and 0.14 mg/mL of [USP Sumatriptan Succinate Related Compound C RS](#) in *Diluent*

Standard solution: 0.14 mg/mL of [USP Sumatriptan Succinate RS](#) in *Diluent*

Sample solution: 0.14 mg/mL of Sumatriptan Succinate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

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

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for sumatriptan succinate related compound C and sumatriptan are about 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between sumatriptan succinate related compound C and sumatriptan, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sumatriptan succinate ($C_{14}H_{21}N_3O_2S \cdot C_4H_6O_4$) in the portion of Sumatriptan Succinate taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Sumatriptan Succinate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Sumatriptan Succinate in the *Sample solution* (mg/mL)

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

IMPURITIES

• PROCEDURE 1: LIMIT OF SUMATRIPTAN SUCCINATE RELATED COMPOUND A

Buffer: Dissolve 77.1 g of ammonium acetate in 100 mL of water.

Mobile phase: Methanol and *Buffer* (90:10)

Standard solution: 6.25 µg/mL of [USP Sumatriptan Succinate Related Compound A RS](#) in *Mobile phase*

Sample solution: 2.8 mg/mL of Sumatriptan Succinate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sumatriptan related compound A free base in the portion of sumatriptan free base taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times (M_{r3}/M_{r4}) \times 100$$

r_U = peak response of sumatriptan succinate related compound A from the *Sample solution*

r_S = peak response of sumatriptan succinate related compound A from the *Standard solution*

C_S = concentration of [USP Sumatriptan Succinate Related Compound A RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Sumatriptan Succinate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of sumatriptan related compound A, 495.7

M_{r2} = molecular weight of sumatriptan succinate related compound A, 613.8

M_{r3} = molecular weight of sumatriptan succinate, 413.5

M_{r4} = molecular weight of sumatriptan, 295.4

Acceptance criteria: NMT 0.6%

• PROCEDURE 2

Diluent and System suitability solution: Prepare as directed in the Assay.

Buffer: Dissolve 1.7 mL of dibutylamine, 0.6 mL of phosphoric acid, and 3.9 g of monobasic sodium phosphate dihydrate in water. Adjust with a solution of 50% (w/v) sodium hydroxide to a pH of about 7.5, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (20:80)

Identification solution: 3 mg/mL of [USP Sumatriptan Succinate Related Impurities RS](#) in *Mobile phase*

Sample solution: 2.8 mg/mL of Sumatriptan Succinate in *Diluent*

