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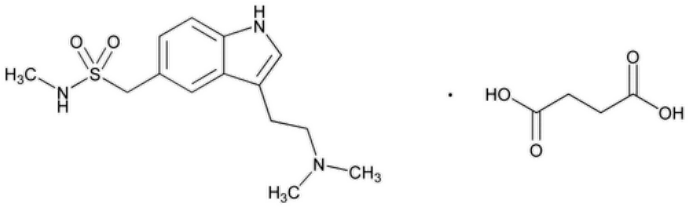
Sumatriptan Succinate



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

Chromatographic system: Prepare as directed in the *Assay*. After making sure that the resolution criteria are met, chromatograph the *Identification solution*, and record the peak responses as directed in the *Analysis*. Identify the peaks according to *Table 1*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Sumatriptan Succinate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of all the peak responses

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
[3-[2-(Dimethylamino-*N*-oxide) ethyl]-1*H*-indol-5-yl]-*N*-methylmethanesulfonamide	0.3	0.2
[3-[2-(Aminoethyl)]-1*H*-indol-5-yl]-*N*-methylmethane sulfonamide	0.4	0.1
[3-[2-(Methylamino)ethyl]-1*H*-indol-5-yl]-*N*-methyl methanesulfonamide	0.6	0.5
Sumatriptan succinate related compound C	0.9	0.5
Sumatriptan	1.0	—
Any individual unspecified impurity	—	0.1
Total impurities[a]	—	1.5

[a] Includes the amount of sumatriptan related compound A determined in the test for *Limit of Sumatriptan Succinate Related Compound A*.

SPECIFIC TESTS

• **Water Determination,** *Method I* ⟨921⟩**:** NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Protect from freezing, and store at a temperature below 30°.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Sumatriptan Succinate RS

USP Sumatriptan Succinate Related Compound A RS

[3-[2-(Dimethylamino)ethyl]-2-[[3-[2-(dimethylamino) ethyl]-1*H*-indol-5-yl]methyl]-1*H*-indol-5-yl]-*N*-methylmethanesulfonamide succinate salt.
$C_{27}H_{37}N_5O_2S \cdot C_4H_6O_4$ 613.77

USP Sumatriptan Succinate Related Compound C RS

[3-[2-(Dimethylamino)ethyl]-1-(hydroxymethyl)-1*H*-indol-5-yl]-*N*-methylmethanesulfonamide succinate salt.
$C_{15}H_{23}N_3O_3S \cdot 0.5C_4H_6O_4$ 384.47

USP Sumatriptan Succinate Related Impurities RS

Mixture of sumatriptan succinate, ▲[3-[2-(methylamino)ethyl]-1*H*-indol-5-yl]-*N*-methylmethanesulfonamide,▲ (ERR 1-Jun-2019) sumatriptan succinate related compound C, [3-[2-(dimethylamino-*N*-oxide)ethyl]-1*H*-indol- 5-yl]-*N*-methylmethanesulfonamide, and [3-[2-(aminoethyl)]-1*H*-

indol-5-yl]-*N*-methyl methanesulfonamide.

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

Topic/Question	Contact	Expert Committee
SUMATRIPTAN SUCCINATE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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