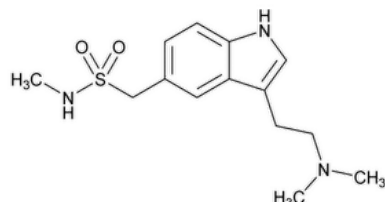


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Sumatriptan



$C_{14}H_{21}N_3O_2S$ 295.40

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

3-[2-(Dimethylamino)ethyl]-*N*-methyl-1*H*-indole-5- methanesulfonamide CAS RN[®]: 103628-46-2; UNII: 8R78F6L9VO.

DEFINITION

Sumatriptan contains NLT 98.0% and NMT 102.0% of sumatriptan ($C_{14}H_{21}N_3O_2S$), 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

Diluent: Dissolve 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 6.5, and dilute with water to 1 L. Mix 750 mL of the this solution with 250 mL of acetonitrile.

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 6.5, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (25:75)

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: 0.1 mg/mL of Sumatriptan 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 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 ($C_{14}H_{21}N_3O_2S$) in the portion of the sample taken:

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

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 in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of sumatriptan, 295.4

M_{r2} = molecular weight of sumatriptan succinate, 413.5

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

IMPURITIES

• PROCEDURE 1: LIMIT OF SUMATRIPTAN 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 mg/mL of Sumatriptan 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%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Sumatriptan 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

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* (25:75)

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

Sample solution: 2 mg/mL of Sumatriptan 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](#).

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between sumatriptan succinate related compound C and sumatriptan

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Sumatriptan 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- <i>N</i> -oxide)ethyl]-1 <i>H</i> -indol-5-yl]- <i>N</i> -methylmethanesulfonamide	0.3	0.2
[3-[2-(Aminoethyl)-1 <i>H</i> -indol-5-yl]- <i>N</i> -methylmethane sulfonamide	0.4	0.1
[3-[2-(Methylamino)ethyl]-1 <i>H</i> -indol-5-yl]- <i>N</i> -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 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 below 30°.

Change to read:

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Sumatriptan RS](#)

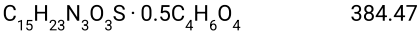
[USP Sumatriptan Succinate RS](#)

[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.
 $\text{C}_{27}\text{H}_{37}\text{N}_5\text{O}_2\text{S} \cdot \text{C}_4\text{H}_6\text{O}_4$ 613.77

[USP Sumatriptan Succinate Related Compound C RS](#)

[3-[2-(Dimethylamino)ethyl]-1-(hydroxymethyl)-1*H*-indol-5-yl]-*N*-methylmethanesulfonamide succinate salt.



[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	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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