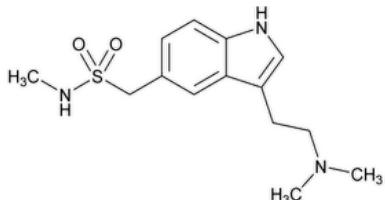


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## Sumatriptan



C<sub>14</sub>H<sub>21</sub>N<sub>3</sub>O<sub>2</sub>S      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<sub>14</sub>H<sub>21</sub>N<sub>3</sub>O<sub>2</sub>S), 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 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)-N-oxide)ethyl]-1 <i>H</i> -indol-5-yl]-N-methylmethanesulfonamide	0.3	0.2
[3-[2-(Aminoethyl)]-1 <i>H</i> -indol-5-yl]-N-methylmethane sulfonamide	0.4	0.1
[3-[2-(Methylamino)ethyl]-1 <i>H</i> -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 <sup>a</sup>	—	1.5

<sup>a</sup> 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.  
 $C_{27}H_{37}N_5O_2S \cdot C_4H_6O_4$  613.77

[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

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	<a href="#">Documentary Standards Support</a>	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM42020 Small Molecules 4

**Chromatographic Database Information:** [Chromatographic Database](#)

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