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Sumatriptan Nasal Spray

DEFINITION

Sumatriptan Nasal Spray is an aqueous, buffered solution of Sumatriptan. It is supplied in a form suitable for nasal administration. It contains NLT 90.0% and NMT 110.0% of the labeled amount of sumatriptan ($C_{14}H_{21}N_3O_2S$).

IDENTIFICATION

Change to read:

- A. [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M](#)▲ (CN 1-MAY-2020)

Sample: To the contents of one vial of Nasal Spray add 1 mL of a saturated [sodium chloride](#) solution. Add 1 mL of a saturated solution of [sodium carbonate](#), and shake vigorously for about 30 s. To the solution so obtained add 2 mL of [isopropyl alcohol](#), shake vigorously for about 30 s, and allow to stand until the phases separate. Transfer the organic phase to a suitable glass vial. Repeat the extraction with a second 2-mL portion of [isopropyl alcohol](#), and transfer the organic phase to the same vial. Evaporate the solution under a stream of nitrogen. Dry the residue in an oven at 100° for 30 min, allow to cool to room temperature in a desiccator, and prepare a mull by the addition of 1–2 drops of mineral oil.

Acceptance criteria: Meets the requirements

Add the following:

- ▲• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲1S (USP41)

ASSAY

Change to read:

• PROCEDURE

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 6.5, and dilute with [water](#) to 1 L.

Mobile phase: [Acetonitrile](#) and *Buffer* (25:75)

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 6.5, and dilute with [water](#) to 1 L. Mix 750 mL of the resulting solution with 250 mL of [acetonitrile](#).

System suitability solution: 0.14 mg/mL of [USP Sumatriptan Succinate RS](#) and 0.07 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: Nominally equivalent to 0.1 mg/mL of sumatriptan in *Diluent* from an appropriate volume of Nasal Spray

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

Column: 4.6-mm × 20-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 4 times the retention of sumatriptan ▲1S (USP41)

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 the labeled amount of sumatriptan ($C_{14}H_{21}N_3O_2S$) in the portion of Nasal Spray 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](#)▲ (ERR 1-Oct-2018) in the *Standard solution* (mg/mL)

C_U = nominal concentration of sumatriptan in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of sumatriptan, ▲295.40▲_{1S} (USP41)

M_{r2} = molecular weight of sumatriptan succinate, ▲413.49▲_{1S} (USP41)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• DELIVERABLE VOLUME

Analysis: Test 10 vials separately. Weigh each vial before and after actuation, and calculate the individual volume delivered, in μL , then calculate the mean volume delivered:

$$\text{Result} = (W_1 - W_2)/D$$

W_1 = weight of the individual vial before actuation (mg)

W_2 = weight of the individual vial after actuation (mg)

D = density of the nasal solution

Acceptance criteria: The volume of each spray delivered is between 80 and 120 μL , and the mean volume is between 90 and 110 μL .

IMPURITIES

Change to read:

• 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)

Diluent: Prepare as directed in the Assay.

Standard solution: ▲0.007 mg/mL▲_{1S} (USP41) of [USP Sumatriptan Succinate Related Compound A RS](#) in *Diluent*

Sample solution: Nominally equivalent to 1.0 mg/mL of sumatriptan in *Diluent* from an appropriate volume of Nasal Spray

Chromatographic system

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

Mode: LC

Detector: UV 282 nm

Column: 4.6-mm × 20-cm; packing [L3](#)

Flow rate: 2 mL/min

Injection volume: 20 μL

▲Run time: NLT 2 times the retention of sumatriptan related compound A▲_{1S} (USP41)

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sumatriptan succinate related compound A in the portion of Nasal Spray taken:



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