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Sumatriptan Injection

DEFINITION

Sumatriptan Injection is a sterile solution of Sumatriptan Succinate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of sumatriptan ($C_{14}H_{21}N_3O_2S$).

IDENTIFICATION

• **A.** The retention time of the major peak in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: Add 1.7 mL of butylamine, 0.66 mL of phosphoric acid, and 3.7 g of monobasic sodium phosphate to 900 mL of water. Mix, and adjust with 1 N sodium hydroxide to a pH of 7.5 ± 0.1. Dilute with water to 1000 mL.

Mobile phase: Acetonitrile and *Buffer* (17:83)

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.14 mg/mL of USP Sumatriptan Succinate RS in *Diluent*

Sample solution: Nominally 0.1 mg/mL of sumatriptan from the Injection in *Diluent*

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 227 nm

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

Flow rate: 1.5 mL/min

Injection size: 10 µL

Run time: About 3 times the retention time of sumatriptan

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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

M_{r1} = molecular weight of sumatriptan free base, 295.40

M_{r2} = molecular weight of sumatriptan succinate, 413.49

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 4.2–5.3
- **Osmolality and Osmolarity ⟨785⟩:** 270–330 mOsmol/kg
- **Particulate Matter in Injections ⟨788⟩:** Meets requirements
- **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 29.2 USP Endotoxin Units/mg of sumatriptan.
- **Sterility Tests ⟨71⟩:** Meets the requirements
- **Other Requirements:** It meets the requirements under *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers, preferably of Type 1 glass. Store between 2° and 30°, protected from light.
- **USP Reference Standards ⟨11⟩**
  USP Sumatriptan Succinate RS

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

Topic/Question	Contact	Expert Committee
SUMATRIPTAN INJECTION	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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