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# Sumatriptan Tablets

## DEFINITION

Sumatriptan Tablets contain 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: 197K](#). ▲ (CN 1-MAY-2020) The IR spectrum exhibits main bands at or near ( $\pm 1$ ) wavenumbers ( $\text{cm}^{-1}$ ) 1708, 1567, 1339, 1300, 1235, 1207, 989, and 844.
- **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 solution A:** 2.9 g/L of monobasic sodium phosphate, 1.3 mL/L of dibutylamine, and 0.4 mL/L of phosphoric acid in water. Adjust with 10 N sodium hydroxide to a pH of 6.5.

**Buffer solution B:** 3.9 g/L of monobasic sodium phosphate. Adjust with 10 N sodium hydroxide to a pH of 6.5 before dilution.

**Mobile phase:** Acetonitrile and *Buffer solution A* (1:3)

**Diluent:** Acetonitrile and *Buffer solution B* (1:3)

**Standard solution:** Equivalent to 0.1 mg/mL of sumatriptan from [USP Sumatriptan Succinate RS](#) in *Diluent*

**Sample stock solution:** Nominally 1–2 mg/mL of sumatriptan from NLT 5 Tablets prepared as follows. Transfer the Tablets to a suitable volumetric flask. Add *Diluent* to fill 60%–80% of the flask volume. Sonicate for 15–20 min with intermittent shaking. Dilute with *Diluent* to volume.

**Sample solution:** Nominally 0.1 mg/mL of sumatriptan in *Diluent* from the *Sample stock solution*. Pass through a suitable filter of 0.45- $\mu\text{m}$  pore size.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 282 nm

**Column:** 4.6-mm  $\times$  25-cm; 5- $\mu\text{m}$  packing L1

**Flow rate:** 1.5 mL/min

**Injection volume:** 10  $\mu\text{L}$

**Run time:** NLT 1.7 times the retention time of sumatriptan

### System suitability

**Sample:** *Standard solution*

### Suitability requirements

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 1.0%

### 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 Tablets 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 the *Sample solution* (mg/mL)

$M_{r1}$  = molecular weight of sumatriptan, 295.4

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

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

### • [DISSOLUTION \(711\)](#)

#### Test 1

**Medium:** 0.01 N hydrochloric acid; 900 mL

**Apparatus 2:** 30 rpm

**Time:** 15 min

**Standard solution:** 0.025 mg/mL of [USP Sumatriptan Succinate RS](#) in *Medium*

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Dilute with *Medium* if necessary.

#### Instrumental conditions

**Mode:** UV

**Detector:** about 282 nm

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sumatriptan ( $C_{14}H_{21}N_3O_2S$ ) dissolved:

$$\text{Result} = (A_u/A_s) \times C_s \times V \times D \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

$A_u$  = absorbance of the *Sample solution*

$A_s$  = absorbance of the *Standard solution*

$C_s$  = concentration of the *Standard solution* (mg/mL)

$V$  = volume of *Medium*, 900 mL

$D$  = dilution factor

$M_{r1}$  = molecular weight of sumatriptan, 295.4

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

$L$  = label claim (mg/Tablet)

**Tolerances:** NLT 80% (Q) of the labeled amount of sumatriptan is dissolved.

**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

**Medium:** 0.01 N hydrochloric acid; 900 mL

**Apparatus 2:** 50 rpm

**Time:** 15 min

**Standard solution:** ( $L/900$ ) mg/mL of [USP Sumatriptan Succinate RS](#) in *Medium*, where  $L$  is the Tablet label claim in mg

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.

#### Instrumental conditions

**Mode:** UV

**Detector:** About 282 nm

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sumatriptan ( $C_{14}H_{21}N_3O_2S$ ) dissolved:

$$\text{Result} = (A_u/A_s) \times C_s \times V \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

$A_u$  = absorbance of the *Sample solution*