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## Entacapone Tablets

### DEFINITION

Entacapone Tablets contain an amount of entacapone equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of entacapone ( $C_{14}H_{15}N_3O_5$ ).

### IDENTIFICATION

**Change to read:**

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K](#) (CN 1-MAY-2020): The sample shows a medium band at about 2216  $cm^{-1}$  and strong bands at about 1628, 1604, 1544, 1512, 1440, 1376, 1348, 1296, 1280, and 1208  $cm^{-1}$  similar to the reference preparation.
- **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

Protect solutions from light.

**Buffer:** 2.1 g/L of monobasic sodium phosphate. Adjust with phosphoric acid to a pH of 2.1.

**Diluent:** Methanol and tetrahydrofuran (70:30)

**Mobile phase:** Methanol, tetrahydrofuran, and *Buffer* (44:2:54)

**Standard solution:** 0.5 mg/mL of [USP Entacapone RS](#) in *Diluent*

**Sample solution:** Nominally 0.5 mg/mL of entacapone prepared as follows. Finely powder NLT 20 Tablets, and transfer a suitable portion of the powder to an appropriate volumetric flask. Add NLT 30% of the final flask volume of tetrahydrofuran, and sonicate for 3 min. Add NLT 30% of the final flask volume of methanol, and shake for 5 min. Dilute with methanol to volume. Centrifuge a portion of this solution, and use the supernatant.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 300 nm

**Column:** 4.6-mm × 25-cm; 5- $\mu$ m packing L11

**Flow rate:** 1 mL/min

**Run time:** 1.5 times the retention time of the entacapone peak

**Injection volume:** 10  $\mu$ L

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Tailing factor:** NMT 1.5

**Relative standard deviation:** NMT 1.5%

#### Analysis

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

Calculate the percentage of the labeled amount of entacapone ( $C_{14}H_{15}N_3O_5$ ) in the portion of Tablets taken:

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

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

$C_S$  = concentration of [USP Entacapone RS](#) in the *Standard solution* (mg/mL)

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

**Acceptance criteria:** 90.0%–110.0%

### PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)

**Test 1**

**Medium:** pH 5.5 phosphate buffer (6.8 g/L of monobasic potassium phosphate in water, adjusted with 1 M sodium hydroxide to a pH of 5.5); 900 mL

**Apparatus 2:** 50 rpm

**Time:** 30 min

**Standard stock solution:** 0.22 mg/mL of [USP Entacapone RS](#), prepared as follows. Transfer a suitable quantity of [USP Entacapone RS](#) to an appropriate volumetric flask, and dissolve in 2% of the flask volume of tetrahydrofuran. Dilute with *Medium* to volume. Protect this solution from light.

**Standard solution:** 0.022 mg/mL of [USP Entacapone RS](#) from the *Standard stock solution* in *Medium*. Protect this solution from light.

**Sample solution:** Pass a portion of the solution through a suitable filter of 20-μm pore size. Dilute with *Medium*, if necessary. Protect this solution from light.

**Instrumental conditions**

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

**Mode:** UV

**Analytical wavelength:** 313 nm

**Path length:** 1 cm

**Blank:** Tetrahydrofuran and *Medium* (0.2:99.8)

**Analysis**

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

Calculate the percentage of the labeled amount of entacapone ( $C_{14}H_{15}N_3O_5$ ) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

$A_U$  = absorbance of the *Sample solution*

$A_S$  = absorbance of the *Standard solution*

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

$L$  = label claim (mg/Tablet)

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

**Tolerances:** NLT 80% (Q) of the labeled amount of entacapone ( $C_{14}H_{15}N_3O_5$ ) is dissolved.

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

**Medium:** pH 5.5 phosphate buffer (6.8 g/L of monobasic potassium phosphate in water, adjusted with 5 M sodium hydroxide to a pH of 5.5); 900 mL

**Apparatus 2:** 50 rpm

**Time:** 45 min

**Standard stock solution:** 0.45 mg/mL of [USP Entacapone RS](#) prepared as follows. Transfer a suitable quantity of [USP Entacapone RS](#) to an appropriate volumetric flask, and dissolve in 5% of the flask volume of methanol. Dilute with *Medium* to volume. Use this solution within 6.5 h.

**Standard solution:** 0.018 mg/mL of [USP Entacapone RS](#) from the *Standard stock solution* in *Medium*. Use this solution within 6.5 h.

**Sample solution:** Pass a portion of the solution under test through a suitable filter. Transfer 2 mL of the filtrate to a 25-mL volumetric flask, and dilute with *Medium* to volume. Pass the resulting solution through a suitable filter of 0.45-μm pore size. Use this solution within 6.5 h.

**Instrumental conditions**

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

**Mode:** UV

**Analytical wavelength:** 313 nm

**Path length:** 1 cm

**Blank:** *Medium*

**Analysis**

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

Calculate the percentage of the labeled amount of entacapone ( $C_{14}H_{15}N_3O_5$ ) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times D \times 100$$

$A_U$  = absorbance of the *Sample solution*

$A_S$  = absorbance of the *Standard solution*

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

$L$  = label claim (mg/Tablet)