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Mirtazapine Orally Disintegrating Tablets

DEFINITION

Mirtazapine Orally Disintegrating Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of mirtazapine ($C_{17}H_{19}N_3$).

IDENTIFICATION

Change to read:

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

Standard solution: Dissolve 30 mg of [USP Mirtazapine RS](#) in a separatory funnel containing 30 mL of water, and add 30 mL of *n*-hexane. Shake vigorously for 5 min. Allow the solution to separate into two layers. Filter the *n*-hexane layer through glass wool, and evaporate to dryness.

Sample solution: Transfer a quantity of finely powdered Tablets, equivalent to 30 mg of mirtazapine, to a separatory funnel. Add 30 mL of water and 30 mL of *n*-hexane. Shake vigorously for 5 min. Allow the solution to separate into two layers. Filter the *n*-hexane layer through glass wool, and evaporate to dryness.

- **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: Acetonitrile and water (50:50)

Diluted phosphoric acid: Water and phosphoric acid (1000:3)

Buffer: Dissolve 1 g of monobasic potassium phosphate and 1.7 g of pentanesulfonic acid sodium salt in 1 L of water. Adjust with *Diluted phosphoric acid* to a pH of 4.7 ± 0.1 , and filter.

Mobile phase: Acetonitrile and *Buffer* (25:75)

Standard stock solution: 0.3 mg/mL of [USP Mirtazapine RS](#) in *Diluent*

Standard solution: 0.036 mg/mL of [USP Mirtazapine RS](#) in *Mobile phase* from the *Standard stock solution*

Sample stock solution: 0.3 mg/mL of mirtazapine in *Diluent* (from NLT 20 Tablets, finely powdered). Sonicate for 15 min with occasional swirling, and shake for 30 min. [NOTE—Alternatively, dissolve 10 Tablets in a volume of a mixture of acetonitrile and water (90:10) to obtain a 0.3 mg/mL solution of mirtazapine. Shake or stir until the mixture is free from lumps.]

Sample solution: Nominally, 0.036 mg/mL of mirtazapine in *Mobile phase* obtained as follows: transfer 40 mL of the *Sample stock solution* into a centrifuge tube, and centrifuge at 3000 rpm for 10 min. Transfer 6.0 mL of the supernatant into a 50-mL volumetric flask, and dilute with *Mobile phase* to volume. Pass the portion through a polypropylene membrane filter of 0.45- μ m pore size. Discard at least the first 5 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 290 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing L1

Flow rate: 1 mL/min

Injection size: 20 μ L

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 mirtazapine ($C_{17}H_{19}N_3$) 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 Mirtazapine RS](#) (mg/mL)

C_u = nominal concentration of mirtazapine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#): NMT 60 s

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 15 min

Sample solution: Sample per [Dissolution \(711\)](#). Pass through a filter of 0.45-μm pore size, and discard the first 5 mL of the filtrate.

Standard solution: 33 μg/mL of [USP Mirtazapine RS](#) in *Medium*

Instrumental conditions

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

Mode: UV

Analytical wavelength: 316 nm

Blank: *Medium*

Cell: 0.5 cm

Analysis: Determine the percentage of mirtazapine ($C_{17}H_{19}N_3$) dissolved:

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

A_u = absorbance of the *Sample solution*

A_s = absorbance of the *Standard solution*

C_s = concentration of [USP Mirtazapine RS](#) in the *Standard solution* (mg/mL)

V = volume, 900 mL

L = label claim of mirtazapine (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of mirtazapine ($C_{17}H_{19}N_3$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

Solution A: Dissolve 7.2 g of tetramethylammonium hydroxide pentahydrate in 4 L of water. Add 1 mL of triethylamine. Adjust with phosphoric acid to a pH of 7.4.

Solution B: Acetonitrile, methanol, and tetrahydrofuran (170:145:85)

Diluent: Acetonitrile and water (50:50)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	61	39
6.0	61	39
10.0	46	54
18.4	46	54
18.5	61	39
22.0	61	39

System suitability solution: 0.3 mg/mL of [USP Mirtazapine RS](#) in *Diluent*