

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Mar-2023
Document Type: USP Monographs
DocId: GUID-7B87953E-3EFC-4A7D-BAFC-16ED1580EC6E_5_en-US
DOI: https://doi.org/10.31003/USPNF_M54295_05_01
DOI Ref: n21y3

© 2025 USPC
Do not distribute

Mirtazapine Tablets

DEFINITION

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

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Extraction mixture: *n*-Hexane and water (1:1)

Sample: Transfer an amount equivalent to 30 mg of mirtazapine from finely powdered Tablets to a suitable centrifuge tube. Add *Extraction mixture* to obtain a solution of 1 mg/mL of mirtazapine in *n*-hexane. Shake for 5 min, and centrifuge. Decant, and evaporate the supernatant.

Standard: Dissolve [USP Mirtazapine RS](#) in *Extraction mixture* to obtain a solution having a concentration of about 1 mg/mL of mirtazapine in *n*-hexane. Shake for 5 min, and centrifuge. Decant, and evaporate the supernatant.

- **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 (1:1)

Buffer: Dissolve 18.0 g of tetramethylammonium hydroxide pentahydrate in 950 mL of water. Adjust with phosphoric acid to a pH of 7.4, and dilute with water to 1 L.

Mobile phase: Acetonitrile, methanol, tetrahydrofuran, and *Buffer* (15:12.5:7.5:65)

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

Sample solution: Nominally 0.3 mg/mL of mirtazapine (from an amount equivalent to the weight of 1 Tablet from NLT 20 finely powdered Tablets) in *Diluent*. Shake vigorously for 10 min, centrifuge an aliquot, and use the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 290 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 7000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.5%

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](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS• **[DISSOLUTION \(711\)](#)****Medium:** 0.1 N hydrochloric acid; 900 mL**Apparatus 2:** 50 rpm**Time:** 15 min**Sample solution:** Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.**Standard solution:** [USP Mirtazapine RS](#) in *Medium* in a concentration similar to the one expected in the *Sample solution***Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 315 nm**Analysis****Samples:** *Sample solution* and *Standard solution*Calculate the percentage of the labeled amount 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 of the *Medium*, 900 mL L = label claim (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****Change to read:**• **ORGANIC IMPURITIES****Diluent, Buffer, and Mobile phase:** Proceed as directed in the Assay.**System suitability solution:** 1.5 mg/mL of [USP Mirtazapine Resolution Mixture RS](#) in *Diluent***Standard solution:** 0.015 mg/mL of [USP Mirtazapine RS](#) in *Diluent***Sample solution:** 1.5 mg/mL of mirtazapine (from an amount equivalent to the weight of 1 Tablet from NLT 20 finely powdered Tablets) in *Diluent*. Shake vigorously for 10 min, centrifuge an aliquot, and use the clear supernatant.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 240 nm**Column:** 4.6-mm × 25-cm; packing L1**Column temperature:** 40°**Flow rate:** 1.5 mL/min**Injection volume:** 10 µL**Run time:** 2 times the retention time of mirtazapine**System suitability****Samples:** *System suitability solution* and *Standard solution*[NOTE—The relative retention times are listed in [Table 1](#).]**Suitability requirements****Resolution:** NLT 1.5 between acyclomirtazapine methyl derivative (impurity E) and ▲10-ketomirtazapine▲ (ERR 1-Mar-2023) (impurity F),
*System suitability solution***Tailing factor:** NMT 2.0, *Standard solution***Relative standard deviation:** NMT 10.0%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

 r_U = peak response of any impurity from the *Sample solution*