

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2022
Document Type: USP Monographs
DocId: GUID-CB98788E-B231-41BF-A188-6A715738C91B_3_en-US
DOI: https://doi.org/10.31003/USPNF_M2644_03_01
DOI Ref: soa5o

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Olanzapine Orally Disintegrating Tablets

DEFINITION
Olanzapine Orally Disintegrating Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of olanzapine (C₁₇H₂₀N₄S).

- IDENTIFICATION**
- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197K
Standard: Add 25 mg of [USP Olanzapine RS](#) to a suitable container containing 10 mL of [water](#). Centrifuge for 5 min, and discard the supernatant. Dry the olanzapine under vacuum for 1 h at 60°.
Sample: Place 1 Tablet in 10 mL of [water](#) in a centrifuge tube. Centrifuge for 5 min. Wash the precipitate with 5 mL of [water](#), and centrifuge for 5 min. Discard the [water](#), and repeat the process a third time. Dry the olanzapine under vacuum for 1 h at 60°.
Acceptance criteria: Meet the requirements
 - 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**
Solution A: [Acetonitrile](#) and [water](#) (20:80). Add 2 mL of [perchloric acid](#) to each liter of the mixture.
Solution B: [Acetonitrile](#) and [water](#) (60:40). Add 2 mL of [perchloric acid](#) to each liter of the mixture.
Diluent: [Acetonitrile](#) and [water](#) (35:65)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	87	13
10	87	13
20	0	100
26	0	100
26.1	87	13
36	87	13

System suitability solution: 0.1 mg/mL of [USP Olanzapine RS](#) and 10 µg/mL of [USP Olanzapine Related Compound C RS](#) in *Diluent*
Standard solution: 0.1 mg/mL of [USP Olanzapine RS](#) in *Diluent*
Sample stock solution: 0.5–0.6 mg/mL of olanzapine from Tablets (NLT 10), prepared as follows. Transfer the Tablets to a suitable volumetric flask. Add *Diluent* to fill about 80% of the flask volume. Shake mechanically for 10 min, and dilute with *Diluent* to volume.
Sample solution: Nominally 0.1–0.12 mg/mL of olanzapine from the *Sample stock solution* in *Diluent*
Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 260 nm
Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)
Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between the olanzapine and olanzapine related compound C peaks, *System suitability solution*

Tailing factor: NMT 2.0 for the olanzapine peak, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of olanzapine ($C_{17}H_{20}N_4S$) in the portion of Tablets taken:

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

r_U = peak response of olanzapine from the *Sample solution*

r_S = peak response of olanzapine from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#)

Test 1: NMT 10 s for each of 6 units

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

Acceptance criteria: NMT 30 s

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 10 min

Standard solution: (L/900) mg/mL of [USP Olanzapine RS](#) in *Medium*

Sample solution: A portion of the solution under test may be either centrifuged or filtered through a suitable membrane filter of 0.45- μ m pore size. Discard the first few milliliters. The filtrate or centrifugate may be suitably diluted.

Determine the amount of olanzapine ($C_{17}H_{20}N_4S$) dissolved by using either the *Spectrometric procedure* or *Chromatographic procedure*.

Spectrometric procedure

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 344 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of olanzapine ($C_{17}H_{20}N_4S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution factor of the *Sample solution* (USP 1-Aug-2022)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)