

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2019
 Document Type: USP Monographs
 DocId: GUID-422285D3-F269-47AD-AB97-4A487D45EE36_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M756_02_01
 DOI Ref: uy97g

© 2025 USPC
 Do not distribute

Risperidone Orally Disintegrating Tablets

DEFINITION

Risperidone Orally Disintegrating Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of risperidone ($C_{23}H_{27}FN_4O_2$).

IDENTIFICATION

Change to read:

• **A.** (USP 1-May-2019) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. (USP 1-May-2019)

ASSAY

Change to read:

PROCEDURE

Mobile phase: Acetonitrile, [trifluoroacetic acid](#), and [water](#) (200:1.5:800). Adjust with [ammonium hydroxide](#) to a pH of 3.0.

Diluent: [Methanol](#) and 0.1 N [hydrochloric acid](#) (40:60)

System suitability solution: 0.1 mg/mL of [USP Risperidone Related Compounds Mixture RS](#) prepared as follows. Transfer a suitable quantity of [USP Risperidone Related Compounds Mixture RS](#) to a suitable volumetric flask and dissolve (USP 1-May-2019) in 20% of the flask volume of [methanol](#). Dilute with *Diluent* to volume.

Standard solution: 0.1 mg/mL of [USP Risperidone RS](#) in *Diluent*

Sample solution: Nominally (USP 1-May-2019) 0.1 mg/mL of risperidone in *Diluent* from NLT 13 Tablets. [NOTE—Sonicate for 30 min.]

Chromatographic system

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

Mode: LC

Detector: UV 275 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm. (USP 1-May-2019)

Column: 3.0-mm × 15-cm; 3.5-μm packing [L1](#)

Flow rate: 0.8 mL/min

Injection volume: 10 μL

Run time: NLT 2.2 (USP 1-May-2019) times the retention time of risperidone

System suitability

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

[NOTE—For relative retention times, see [Table 1](#). (USP 1-May-2019)]

Suitability requirements

Resolution: NLT 1.8 between Z-oxime and bicyclorisperidone, *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 risperidone (USP 1-May-2019) ($C_{23}H_{27}FN_4O_2$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#)

Test 1: NMT 30 s

Test 2: NMT 60 s. [NOTE—If the product complies with this test, the labeling indicates that the product meets USP *Disintegration Test 2*.]

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 2: 50 rpm

Time: 10 min

Buffer: 8.7 g/L of [dibasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 7.8.

Mobile phase: Acetonitrile and *Buffer* (45:55)

Standard solution: ($L/500$) mg/mL of [USP Risperidone RS](#) in *Medium*, where L is the label claim in mg/Tablet

Sample solution: Pass 10 mL of the solution under test through a suitable $\blacktriangle$ (USP 1-May-2019) filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm $\times$ 10-cm; 5- μ m packing [L1](#)

Column temperature: $28 \pm 3^\circ$

Flow rate: 2 mL/min

Injection volume: 20 μ L. [NOTE—Use 40 μ L for Tablets labeled to contain 0.5 mg of risperidone.]

Run time: $\blacktriangle$ NLT $\blacktriangle$ (USP 1-May-2019) 2 times the retention time of risperidone

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $\blacktriangle$ the labeled amount of risperidone $\blacktriangle$ (USP 1-May-2019) ($C_{23}H_{27}FN_4O_2$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

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

Change to read:

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

$\blacktriangle$ $\blacktriangle$ (USP 1-May-2019)