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Risperidone Oral Solution

DEFINITION

Risperidone Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of risperidone ($C_{23}H_{27}FN_4O_2$). It may contain a suitable preservative.

IDENTIFICATION

• **A.** 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-2021)

ASSAY

Change to read:

• PROCEDURE

Buffer: 5.0 g/L of [ammonium acetate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer* ▲(22:78)▲ (USP 1-May-2021)

System suitability solution: ▲250 µg/mL▲ (USP 1-May-2021) of [USP Risperidone Related Compounds Mixture RS](#) prepared as follows. Weigh [USP Risperidone Related Compounds Mixture RS](#) into a suitable volumetric flask. Dissolve first in 20% of the flask volume of [methanol](#). Add 20% of the flask volume of [water](#) followed by 50% of the flask volume of *Buffer*, and allow to cool to room temperature. Dilute with [methanol](#) to volume.

Standard stock solution: ▲1000 µg/mL▲ (USP 1-May-2021) of [USP Risperidone RS](#) in [methanol](#)

Standard solution: ▲200 µg/mL▲ (USP 1-May-2021) of [USP Risperidone RS](#) prepared from the *Standard stock solution* as follows. Transfer 5.0 mL of the *Standard stock solution* to a 25-mL volumetric flask. Add 5.0 mL of [water](#) followed by 12.5 mL of *Buffer*, and allow to cool to room temperature. Dilute with [methanol](#) to volume.

Sample solution: ▲Nominally 200 µg/mL of risperidone▲ (USP 1-May-2021) from Oral Solution as follows. Transfer an amount of Oral Solution, equivalent to 5 mg of risperidone to a 25-mL volumetric flask, add 12.5 mL of *Buffer*, fill with [methanol](#) almost to volume, and mix well. Allow to cool to room temperature, and dilute with [methanol](#) to volume.

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 190–400 nm.▲ (USP 1-May-2021)

Column: 4.6-mm × 10-cm; 3-µm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: ▲NLT▲ (USP 1-May-2021) 2 times the retention time of risperidone

System suitability

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

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between bicyclorisperidone and ▲risperidone▲ (USP 1-May-2021) Z-oxime, *System suitability solution*

Relative standard deviation: NMT ▲1.0%▲ (USP 1-May-2021) *Standard solution*

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of risperidone ($C_{23}H_{27}FN_4O_2$) in the portion of Oral Solution 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* ▲(μg/mL)▲ (USP 1-May-2021) C_U = nominal concentration of risperidone in the *Sample solution* ▲(μg/mL)▲ (USP 1-May-2021)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS**

- [DELIVERABLE VOLUME \(698\)](#): Meets the requirements

IMPURITIES**Change to read:**

- **ORGANIC IMPURITIES**

Buffer, Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.**Standard stock solution:** 5 μg/mL of [USP Risperidone RS](#) in [methanol](#)**Standard solution:** 1 μg/mL of [USP Risperidone RS](#) from the *Standard stock solution* prepared as follows. Transfer 5.0 mL of the *Standard stock solution* to a 25-mL volumetric flask. Add 5.0 mL of [water](#) followed by 12.5 mL of *Buffer*, and allow to cool to room temperature. Dilute with [methanol](#) to volume.**▲Sensitivity solution:** 0.2 μg/mL of [USP Risperidone RS](#) from the *Standard stock solution* prepared as follows. Transfer 1.0 mL of the *Standard stock solution* to a 25-mL volumetric flask. Add 5.0 mL of [water](#) followed by 12.5 mL of *Buffer*, and allow to cool to room temperature. Dilute with [methanol](#) to volume.▲ (USP 1-May-2021)**System suitability****Samples:** *System suitability solution*, *Standard solution*, and ▲*Sensitivity solution*▲ (USP 1-May-2021)[NOTE—See [Table 1](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 1.5 between bicyclorisperidone and ▲risperidone▲ (USP 1-May-2021) *Z*-oxime, *System suitability solution***Relative standard deviation:** ▲NMT 5%,▲ (USP 1-May-2021) *Standard solution***▲Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲ (USP 1-May-2021)**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each ▲degradation product▲ (USP 1-May-2021) in the portion of Oral Solution taken:

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

 r_U = peak response of each ▲degradation product▲ (USP 1-May-2021) 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* ▲(μg/mL)▲ (USP 1-May-2021) C_U = nominal concentration of risperidone in the *Sample solution* ▲(μg/mL)▲ (USP 1-May-2021) F = relative response factor (see [Table 1](#))**Acceptance criteria:** See [Table 1](#). ▲The reporting threshold is 0.10%.▲ (USP 1-May-2021)**Table 1**