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Galantamine Oral Solution

DEFINITION

Galantamine Oral Solution contains an amount of galantamine hydrobromide ($C_{17}H_{21}NO_3 \cdot HBr$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of galantamine ($C_{17}H_{21}NO_3$). Galantamine Oral Solution also contains one or more suitable preservatives.

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.

ASSAY

Change to read:

PROCEDURE

- ▲ (USP 1-Aug-2020)
- Solution A:** [Acetonitrile](#) and [water](#) (1:99)
- Solution B:** 5 mg/mL of [ammonium acetate](#) in *Solution A*
- Solution C:** [Acetonitrile](#)
- Solution D:** [Water](#)
- Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)	Solution D (%)
0	50	3	47
25	50	35	15
27	50	3	47
32	50	3	47

Diluent: 5 mg/mL of [ammonium acetate](#) in [water](#)

System suitability solution: 0.26 mg/mL of [USP Galantamine Hydrobromide Related Compounds Mixture RS](#) prepared as follows. Transfer a suitable quantity of [USP Galantamine Hydrobromide Related Compounds Mixture RS](#) to a suitable flask, and dissolve in 3% of the flask volume of [methanol](#). Dilute with *Diluent* to volume.

Standard solution: 0.26 mg/mL of [USP Galantamine Hydrobromide RS](#) (equivalent to 0.2 mg/mL of galantamine) prepared as follows. Transfer a suitable quantity of [USP Galantamine Hydrobromide RS](#) to an appropriate flask, and dissolve in 3% of the flask volume of [methanol](#). Dilute with *Diluent* to volume.

Sample solution: Nominally 0.2 mg/mL of galantamine from Oral Solution prepared as follows. Transfer a suitable volume of Oral Solution to an appropriate volumetric flask. Add 3% of the flask volume of [methanol](#), and dilute with *Diluent* to volume.

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

Mode: LC

Detector: UV 230 nm

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

Flow rate: 1.5 mL/min

Injection volume: 10 µL

▲ (USP 1-Aug-2020)

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 5 between galantamine and 6S-galantamine, ▲ (USP 1-Aug-2020) *System suitability solution*

Tailing factor: NMT 1.3, *Standard solution*

Relative standard deviation: NMT ▲1.0%, ▲ (USP 1-Aug-2020) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of galantamine ($C_{17}H_{21}NO_3$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response ▲ of galantamine ▲ (USP 1-Aug-2020) from the *Sample solution*

r_S = peak response ▲ of galantamine ▲ (USP 1-Aug-2020) from the *Standard solution*

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

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

M_{r1} = molecular weight of galantamine, 287.35

M_{r2} = molecular weight of galantamine hydrobromide, 368.27

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

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

IMPURITIES

Change to read:

- **ORGANIC IMPURITIES**

▲ (USP 1-Aug-2020)

Mobile phase, Diluent, System suitability solution, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.5 µg/mL of [USP Galantamine Hydrobromide RS](#) prepared as follows. Transfer a suitable quantity of [USP Galantamine Hydrobromide RS](#) to an appropriate flask, and dissolve in 3% of the flask volume of methanol. Dilute with *Diluent* to volume.

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 5 between galantamine and 6S-galantamine, ▲ (USP 1-Aug-2020) *System suitability solution*

Tailing factor: NMT 1.3, *Standard solution*

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

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each degradation product from the *Sample solution*

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