

Galantamine Tablets

DEFINITION
Galantamine Tablets contain an amount of Galantamine Hydrobromide equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of galantamine (C₁₇H₂₁NO₃).

IDENTIFICATION
Change to read:

- **A.** ▲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)
- **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
Change to read:

- **PROCEDURE**
Buffer solution: 5.34 g/L of [dibasic sodium phosphate dihydrate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 6.5.
Solution A: ▲[Methanol](#)▲ (USP 1-May-2021) and *Buffer solution* (1:19)
Solution B: ▲[Acetonitrile](#) and [methanol](#)▲ (USP 1-May-2021) (19:1)
Mobile phase: See [Table 1](#).

Table 1		
Time (min)	Solution A (%)	Solution B (%)
0	100	0
40.0	75	25
45.0	60	40
46.0	40	60
55.0	40	60
56.0	100	0
61.0	100	0

Diluent: Dissolve 35.4 g of [edetate disodium](#) in 950 mL of [water](#), and add 50 mL of ▲[methanol](#).▲ (USP 1-May-2021) [NOTE—First dissolve in [water](#), and then add ▲[methanol](#).]

System suitability solution: 0.6 mg/mL of [USP Galantamine Hydrobromide Related Compounds Mixture RS](#) in *Diluent*▲ (USP 1-May-2021)

Standard solution: 0.62 mg/mL of [USP Galantamine Hydrobromide RS](#)▲(equivalent to 0.48 mg/mL of galantamine)▲ (USP 1-May-2021) in *Diluent*

Sample solution: ▲Nominally▲ (USP 1-May-2021) 0.48 mg/mL of galantamine from powdered Tablets (NLT 10) in *Diluent*. Pass through a PTFE filter of 0.45-µm or finer pore size.

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 230 nm. ▲For *Identification A*, use a diode array detector in the range of 200–300 nm.▲ (USP 1-May-2021)**Column:** 4.6-mm × 10-cm; 3-μm packing [L1](#)**Column temperature:** 35°**Flow rate:** 1.5 mL/min**Injection volume:** 20 μL**System suitability****Samples:** ▲*System suitability solution* and▲ (USP 1-May-2021) *Standard solution*▲[NOTE—See [Table 2](#) for the relative retention times.]▲ (USP 1-May-2021)**Suitability requirements**▲**Resolution:** NLT 1.5 between galantamine *N*-oxide and dihydrogalantamine, *System suitability solution*▲ (USP 1-May-2021)**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 galantamine (C₁₇H₂₁NO₃) in the portion of Tablets taken:

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

 r_U = peak response from the *Sample solution* r_S = peak response 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****Change to read:**

- [DISSOLUTION \(711\)](#).

Test 1**Medium:** [Water](#); 500 mL**Apparatus 2:** 50 rpm**Time:** 20 min▲Analyze the sample under test using either the *Instrumental procedure* or *Chromatographic procedure*.**Instrumental procedure**▲ (USP 1-May-2021)**Standard solution:** (L/400) mg/mL of [USP Galantamine Hydrobromide RS](#) in *Medium*, where L is the label claim in mg▲/Tablet▲ (USP 1-May-2021)**Sample solution:** Pass ▲a portion▲ (USP 1-May-2021) of the solution through a suitable filter of 0.2-μm pore size.**Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 288 nm**Cell:** 5-cm for 4-mg and 8-mg Tablets; 1-cm for 12-mg Tablets**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of galantamine (C₁₇H₂₁NO₃) dissolved in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times (M_{r1}/M_{r2}) \times V \times 100$$

A_U = absorbance of galantamine from the *Sample solution*

A_S = absorbance of galantamine from the *Standard solution*

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

L = label claim (mg/Tablet)

M_{r1} = molecular weight of galantamine, 287.35

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

V = volume of *Medium*, 500 mL

▲Chromatographic procedure

Buffer: 3.45 g/L of [monobasic sodium phosphate](#) in [water](#). To each liter, add 1 mL of [triethylamine](#). Adjust with [phosphoric acid](#) to a pH of 4.5.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (10:10:80), filtered and deaerated

Standard solution: (L/400) mg/mL of [USP Galantamine Hydrobromide RS](#) in [water](#), where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution through a suitable filter of 0.45-μm pore size. Use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 2 times the retention time of galantamine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak area of galantamine from the *Sample solution*

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

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

L = label claim (mg/Tablet)

M_{r1} = molecular weight of galantamine, 287.35

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

V = volume of *Medium*, 500 mL ▲ (USP 1-May-2021)

Tolerances: NLT 80% (Q) of the labeled amount of galantamine ($C_{17}H_{21}NO_3$) is dissolved.

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

▲**Medium:** [Water](#); 500 mL

Apparatus 2: 50 rpm