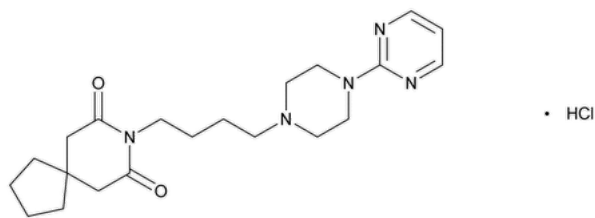


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Buspirone Hydrochloride



$C_{21}H_{31}N_5O_2 \cdot HCl$ 421.96
8-Azaspiro[4,5]decane-7,9-dione, 8-[4-[4-(2-pyrimidinyl)-1-piperazinyl]butyl]-, monohydrochloride;
N-[4-[4-(2-Pyrimidinyl)-1-piperazinyl]butyl]-1,1-cyclopentanediacetamide monohydrochloride CAS RN®: 33386-08-2; UNII: 207LT9J9OC.

DEFINITION
Buspirone Hydrochloride contains NLT 97.5% and NMT 102.5% of buspirone hydrochloride ($C_{21}H_{31}N_5O_2 \cdot HCl$), calculated on the as-is basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#).
Sample solution: 10 mg/mL in water
Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**
Buffer A: 6.8 g/L of monobasic potassium phosphate and 0.93 g/L of sodium 1-hexanesulfonate monohydrate. Adjust with phosphoric acid to a pH of 3.4.
Buffer B: 3.4 g/L of monobasic potassium phosphate and 3.52 g/L of sodium 1-hexanesulfonate monohydrate. Adjust with phosphoric acid to a pH of 2.2.
Solution A: Acetonitrile and *Buffer A* (5:95)
Solution B: Acetonitrile and *Buffer B* (75:25)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
6	90	10
34	42	58
45	42	58
55	0	100
56	100	0
60	100	0
61	90	0

Diluent: *Solution A*

Impurities stock solution: 0.25 mg/mL each of [USP Buspirone Related Compound A RS](#), [USP Buspirone Related Compound G RS](#), [USP Buspirone Related Compound K RS](#), [USP Buspirone Related Compound L RS](#), and [USP Buspirone Related Compound N RS](#) in acetonitrile

System suitability solution: 1.0 mg/mL of [USP Buspirone Hydrochloride RS](#) and 0.001 mg/mL each of [USP Buspirone Related Compound A RS](#), [USP Buspirone Related Compound G RS](#), [USP Buspirone Related Compound K RS](#), [USP Buspirone Related Compound L RS](#), and [USP Buspirone Related Compound N RS](#) in *Diluent*, from *Impurities stock solution*

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

Sample solution: 0.1 mg/mL of Buspirone Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between buspirone and buspirone related compound G peaks, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 0.92%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of buspirone hydrochloride ($C_{21}H_{31}N_5O_2 \cdot HCl$) in the portion of Buspirone Hydrochloride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Buspirone Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.5%–102.5% on the as-is basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

• **ORGANIC IMPURITIES**

Buffer A, Buffer B, Solution A, Solution B, Mobile phase, Diluent, Impurities stock solution, and System suitability solution: Proceed as directed in the Assay.

Standard solution: 0.001 mg/mL each of [USP Buspirone Hydrochloride RS](#), [USP Buspirone Related Compound A RS](#), [USP Buspirone Related Compound G RS](#), [USP Buspirone Related Compound K RS](#), [USP Buspirone Related Compound L RS](#), and [USP Buspirone Related Compound N RS](#) in *Diluent*

Sample solution: 1.0 mg/mL of Buspirone Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 210 and 240 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—See [Table 2](#) and [Table 3](#) for relative retention times.]

Suitability requirements

Resolution at 240 nm: NLT 2.0 between buspirone and buspirone related compound G peaks, *System suitability solution*

Resolution at 210 nm: NLT 4.0 between buspirone related compound L and buspirone related compound N peaks, *System suitability solution*

Relative standard deviation: NMT 2.0% for each peak, *Standard solution*