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Buspirone Hydrochloride Tablets

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DEFINITION

Buspirone Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of buspirone hydrochloride ($C_{21}H_{31}N_5O_2 \cdot HCl$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Sample: Grind 20 Tablets to a fine powder, add 50 mL of [chloroform](#), stir for 3–5 min, and filter into a 250-mL evaporating flask. Evaporate the solution with the aid of a rotary evaporator to dryness at low heat. Use the residue.

Acceptance criteria: Meet the requirements

- **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

• **PROCEDURE**

Buffer A: 6.8 g/L of [monobasic potassium phosphate](#) and 0.93 g/L of [sodium 1-hexanesulfonate monohydrate](#), adjusted 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](#), adjusted 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	10

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 the *Impurities stock solution*

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

Sample solution: Nominally 0.1 mg/mL of buspirone hydrochloride from NLT 20 finely powdered Tablets in *Diluent*, prepared as follows:
Transfer a suitable amount of the powder to a suitable volumetric flask. Add 60% of the flask volume of *Diluent*, and sonicate for 30 min.

Allow the solution to cool to room temperature, and then dilute with *Diluent* to volume. Centrifuge the solution and filter the supernatant. Further dilute the filtrate with *Diluent* as needed.

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 the buspirone and buspirone related compound G peaks, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of buspirone hydrochloride ($C_{21}H_{31}N_5O_2 \cdot HCl$) in the portion of Tablets 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 = nominal concentration of buspirone hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: 0.01 N [hydrochloric acid](#); 500 mL

Apparatus 2: 50 rpm ▲ with suitable sinker, if needed ▲ (RB 1-Jun-2021)

Time: 30 min

Sample solution: Filter a portion of the solution under test, and dilute with *Medium* as needed.

Standard solution: [USP Buspirone Hydrochloride RS](#) in *Medium* having a concentration similar to that expected in the *Sample solution*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum at about 235 ▲ or 237 ▲ (RB 1-Jun-2021) nm

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of the labeled amount of buspirone hydrochloride ($C_{21}H_{31}N_5O_2 \cdot HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of buspirone hydrochloride from the *Standard solution*

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

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of buspirone hydrochloride ($C_{21}H_{31}N_5O_2 \cdot HCl$) is dissolved.

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

IMPURITIES

• **ORGANIC IMPURITIES**