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Bupropion Hydrochloride Extended-Release Tablets

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DEFINITION

Bupropion Hydrochloride Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$).

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
Sample: Crush 1 Tablet using a mortar and pestle. Prepare an approximate 1% (w/w) dispersion of the sample in [potassium bromide](#).
Acceptance criteria: The *Sample* shows strong bands at about 1690, 1560, and 1240 cm^{-1} and a weaker band at about 740 cm^{-1} , similar to the reference preparation.
- B.** The retention time of the major peak of *Sample solution A* or *Sample solution B* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

- PROCEDURE**
Diluent 1: [Methanol](#) and [0.001 N hydrochloric acid TS](#) (20:80)
Solution A: [Acetonitrile](#), [trifluoroacetic acid](#), and [water](#) (10: 0.04: 90)
Solution B: [Acetonitrile](#), [trifluoroacetic acid](#), and [water](#) (95: 0.03: 5)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
3.4	87	13
10.0	15	85
10.1	0	100
13.0	0	100
13.2	90	10
19.0	90	10

System suitability stock solution: 0.02 mg/mL of [USP Bupropion Related Compound C RS](#) and 0.2 mg/mL of [USP Bupropion Related Compound F RS](#) in [methanol](#)

System suitability solution: 0.002 mg/mL of bupropion related compound C and 0.02 mg/mL of bupropion related compound F from the *System suitability stock solution* in *Diluent 1*

Standard solution: 0.6 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Diluent 1*

Sample stock solution A: Transfer a number of Tablets, intact or crushed, to a suitable homogenizer vessel containing sufficient [methanol](#) to obtain a concentration of 3.0 mg/mL of bupropion hydrochloride. Immediately homogenize the sample for 30 s at 20,000 rpm. Allow extraction for 3 min, and follow by two additional 10-s pulses, each at 20,000 rpm, pausing 3 min between these pulses to ensure complete extraction. Pass a portion of the solution through a nylon filter of 0.45- μ m pore size, discarding the first 2–4 mL of the filtrate.

Sample solution A: Nominally 0.6 mg/mL of bupropion hydrochloride from *Sample stock solution A* in [0.001 N hydrochloric acid TS](#). Alternatively, the *Sample solution* can be prepared as follows.

Buffer: Dissolve 100 g of [anhydrous dibasic sodium phosphate](#) in 1 L of water. Add 50 mL of [phosphoric acid](#), stir or sonicate until dissolved, and mix. Adjust with [phosphoric acid](#) to a pH of 3.0.

Diluent 2: [Methanol](#) and *Buffer* (20:80)

Sample stock solution B: Weigh and grind NLT 20 Tablets to prepare a solution having a nominal concentration of 3 mg/mL. Initially add *Diluent 2* (75% of the volume of the flask), stir for 30 min, and sonicate for 15 min. Dilute with *Diluent 2* to volume. Centrifuge a portion of the resulting solution, and use the supernatant.

Sample solution B: Nominally 0.6 mg/mL of bupropion hydrochloride from *Sample stock solution B* in *Diluent 2*

Chromatographic system

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

Mode: LC

Detector: UV 226 nm

Column: 4.6-mm × 10-cm; 3.5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 5 μL

System suitability

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

[NOTE—See [Table 30](#) (RB 1-Aug-2023) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.3 between bupropion related compound F and bupropion related compound C, *System suitability solution*

Tailing factor: NMT 1.9, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution A* or *Sample solution B*

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) in the portion of Tablets taken:

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

r_U = peak response of bupropion hydrochloride from *Sample solution A* or *Sample solution B*

r_S = peak response of bupropion hydrochloride from the *Standard solution*

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

C_U = nominal concentration of bupropion hydrochloride in *Sample solution A* or *Sample solution B* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

For products labeled for dosing every 12 h

Test 1

Medium: [Water](#); 900 mL, deaerated, if necessary

Apparatus 2: 50 rpm

Times: 1, 4, and 8 h

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet. Dilute with *Medium*, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 298 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) in the sample withdrawn from the vessel at time point i :

$$\text{Result}_i = (A_U/A_S) \times C_S \times D$$

A_U = absorbance from the *Sample solution* at time point i

A_s = absorbance from the *Standard solution*

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

D = dilution factor for the *Sample solution*, if needed

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at each time point (i):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_s)] + (C_1 \times V_s)\} \times (1/L) \times 100$$

$$\text{Result}_3 = \{[C_3 \times [V - (2 \times V_s)]] + [(C_2 + C_1) \times V_s]\} \times (1/L) \times 100$$

C_i = concentration of bupropion hydrochloride in the portion of the sample withdrawn at time point i (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

V_s = volume of *Sample solution* withdrawn at each time point (mL)

Tolerances: See [Table 2](#).

Table 2

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	25–50
2	4	60–90
3	8	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

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

Medium: 0.1 N hydrochloric acid, pH 1.5 (prepared by transferring 50 mL of [hydrochloric acid](#) to 6000 mL of [water](#), adding 18 g of [sodium hydroxide](#), mixing, and adjusting with either diluted [sodium hydroxide](#) or [hydrochloric acid](#) to a pH of 1.5); 900 mL, deaerated

Apparatus 1: 50 rpm

Times: 1, 2, 4, and 6 h

Buffer: 3.45 g of [monobasic sodium phosphate](#) in 996 mL of [water](#). Add 4.0 mL of [triethylamine](#), and adjust with [phosphoric acid](#) to a pH of 2.80.

Mobile phase: [Methanol](#) and *Buffer* (35:65)

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet

Sample solution: Use portions of the solution under test, and pass through a nylon filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 298 nm

Column: 4.6-mm $\times$ 15-cm; packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.

Tolerances: See [Table 3](#).

Table 3

Time (h)	Amount Dissolved (%)
1	25–50
2	40–65
4	65–90
6	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm. Use wire coil sinkers, if necessary.

Times: 1, 2, 4, and 6 h

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet. Dilute with *Medium*, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 250 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.

Tolerances: See [Table 4](#).

Table 4

Time (h)	Amount Dissolved (for Tablets that contain 200 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain all other strengths of bupropion hydrochloride) (%)
1	30–50	30–55
2	45–65	50–75
4	65–85	70–90
6	NLT 78	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

Test 5: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 5*.

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Times: 1, 3, and 6 h

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet. Dilute with *Medium*, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 298 nm**Cell:** 0.5 cm**Blank:** Medium**Analysis****Samples:** Standard solution and Sample solutionDetermine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.**Tolerances:** See [Table 5](#).**Table 5**

Time (h)	Amount Dissolved (%)
1	35–55
3	65–85
6	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

Test 7: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 7*.**Medium:** 0.1 N hydrochloric acid, pH 1.5 (prepared by transferring 50 mL of [hydrochloric acid](#) to 6000 mL of [water](#), adding 18 g of [sodium hydroxide](#), mixing, and adjusting with either diluted [sodium hydroxide](#) or [hydrochloric acid](#) to a pH of 1.5); 900 mL, deaerated**Apparatus 1:** 50 rpm**Times:** 1, 2, 4, and 6 h**Buffer:** 3.45 g of [monobasic sodium phosphate](#) in 996 mL of [water](#). Add 4.0 mL of [triethylamine](#), and adjust with [phosphoric acid](#) to a pH of 2.80.**Mobile phase:** [Methanol](#) and Buffer (45:55)**Standard solution:** ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in Medium, where L is the label claim, in mg/Tablet**Sample solution:** Use portions of the solution under test, and pass through a nylon filter of 0.45- μ m pore size.**Chromatographic system**(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 298 nm**Column:** 4.6-mm $\times$ 15-cm; packing [L1](#)**Flow rate:** 1 mL/min**Injection volume:** 20 μ L**System suitability****Sample:** Standard solution**Suitability requirements****Column efficiency:** NLT 2000 theoretical plates**Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** Standard solution and Sample solutionDetermine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.**Tolerances:** See [Table 6](#).**Table 6**

Time (h)	Amount Dissolved (%)
1	25–50
2	45–70
4	NLT 70
6	NLT 80

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The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to

[Dissolution \(711\), Acceptance Table 2.](#)

Test 9: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 9*.

Medium: 0.1 N hydrochloric acid, pH 1.5 (prepared by transferring 50 mL of [hydrochloric acid](#) to 6000 mL of [water](#), adding 18 g of [sodium hydroxide](#), mixing, and adjusting with either diluted [sodium hydroxide](#) or [hydrochloric acid](#) to a pH of 1.5); 900 mL

Apparatus 1: 50 rpm

Times: 1, 2, 4, and 8 h

Standard solution: ($L/1000$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 298 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.

Tolerances: See [Table 7](#).

Table 7

Time (h)	Amount Dissolved (%)
1	20–45
2	35–55
4	55–85
8	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to

[Dissolution \(711\), Acceptance Table 2.](#)

Test 10: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 10*.

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Times: 1, 2, 4, and 8 h

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 298 nm

Cell: 0.5 cm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at each time point (i):

$$\text{Result}_i = (A_i/A_s) \times C_s \times V \times (1/L) \times 100$$

A_i = absorbance of bupropion hydrochloride from the *Sample solution* at time point i

A_s = absorbance of bupropion hydrochloride from the *Standard solution*

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



V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: See [Table 8](#).

Table 8

Time Point (<i>i</i>)	Time (h)	Amount Dissolved (%)
1	1	20–40
2	2	35–60
3	4	55–85
4	8	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

Test 17: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 17*.

Medium: 0.1 N hydrochloric acid, pH 1.5 (prepared by transferring 50 mL of [hydrochloric acid](#) to 6 L of [water](#) containing 18 g of [sodium hydroxide](#), mixing, and adjusting with either diluted [sodium hydroxide](#) or diluted [hydrochloric acid](#) to a pH of 1.5); 900 mL, deaerated

Apparatus 1: 50 rpm

Times: 1, 2, 4, and 8 h

Buffer: To each liter of [water](#) add 6.8 g of [monobasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Methanol](#) and *Buffer* (60:40)

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet. Sonication may be used to promote dissolution.

Sample solution: Pass a portion of the solution under test through a suitable filter. [NOTE—A 0.45- μ m nylon membrane filter may be suitable.]

Chromatographic system

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

Mode: LC

Detector: UV 298 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 25 μ L

Run time: NLT 1.5 times the retention time of bupropion

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 concentration (C_i) of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) in the sample withdrawn from the vessel at time point i :

$$\text{Result}_i = (r_i/r_s) \times C_s$$

r_i = peak response of bupropion from the *Sample solution* at time point i

r_s = peak response of bupropion from the *Standard solution*

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

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at each time point (i):

$$\text{Result}_i = C_i \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_s)] + (C_1 \times V_s)\} \times (1/L) \times 100$$

$$\text{Result}_3 = \{(C_3 \times [V - (2 \times V_s)]) + [(C_2 + C_1) \times V_s]\} \times (1/L) \times 100$$

$$\text{Result}_4 = \{(C_4 \times [V - (3 \times V_s)]) + [(C_3 + C_2 + C_1) \times V_s]\} \times (1/L) \times 100$$

C_i = concentration of bupropion hydrochloride in the portion of the sample withdrawn at time point i (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

V_s = volume of *Sample solution* withdrawn at each time point (mL)

Tolerances: See [Table 9](#).

Table 9

Time Point (i)	Time (h)	Amount Dissolved (for Tablets that contain 100 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain 150 mg or 200 mg of bupropion hydrochloride) (%)
1	1	20–40	15–35
2	2	40–60	35–55
3	4	60–85	55–80
4	8	NLT 85	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to

[Dissolution \(711\)](#), [Acceptance Table 2](#).

Test 19: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 19*.

Medium: [Water](#), degassed; 900 mL

Apparatus 1: 50 rpm

Times: 1, 2, 4, and 8 h

Standard stock solution: 0.56 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 10- μ m pore size.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 298 nm

Cell: 1 cm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at each time point (i):

$$\text{Result}_i = (A_i/A_s) \times C_s \times V \times (1/L) \times 100$$

A_i = absorbance of bupropion from the *Sample solution* at time point i

A_s = absorbance of bupropion from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: See [Table 10](#).

Table 10

Time Point (i)	Time (h)	Amount Dissolved (for Tablets that contain 100 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain 150 or 200 mg of bupropion hydrochloride) (%)
1	1	32–52	25–45
2	2	50–70	45–65
3	4	NLT 75	65–85
4	8	NLT 85	NLT 85

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to

[Dissolution \(711\), Acceptance Table 2](#).

For products labeled for dosing every 24 h

Test 4: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL, deaerated

Apparatus 1: 75 rpm

Times: 2, 4, 8, and 16 h

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet. Dilute with *Medium*, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 252 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.

Tolerances: See [Table 11](#).

Table 11

Time (h)	Amount Dissolved (%)
2	NMT 20
4	20–45
8	65–90
16	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to

[Dissolution \(711\), Acceptance Table 2](#).

Test 6: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 6*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL, deaerated

Apparatus 1: 75 rpm

Times: 1, 2, 4, 8, and 12 h

Standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*, where L is the label claim, in mg/Tablet. Dilute with *Medium*, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV-Vis**Analytical wavelength:** 298 nm**Blank:** Medium**Analysis****Samples:** Standard solution and Sample solutionDetermine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.**Tolerances:** See [Table 12](#).**Table 12**

Time (h)	Amount Dissolved (%)
1	15–35
2	25–50
4	40–65
8	65–90
12	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

Test 8: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 8*.**Acid stage medium:** 0.1 N [hydrochloric acid](#); 900 mL**Buffer stage medium:** [pH 6.8 phosphate buffer](#); 900 mL**Apparatus 1:** 75 rpm**Times:** 2 h in *Acid stage medium*; 3, 8, and 16 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.**Standard solution:** ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*, where L is the label claim, in mg/Tablet**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.**Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV-Vis**Analytical wavelength:** 298 nm**Cell:** 0.5 cm**Blank:** Medium**Analysis****Samples:** Standard solution and Sample solutionDetermine the percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved.**Tolerances:** See [Table 13](#).**Table 13**

Time (h)	Amount Dissolved (%)
2	NMT 10
3	10–30
8	60–90
16	NLT 80

The percentages of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\), Acceptance Table 2](#).

Test 11: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 11*.**Acid stage medium:** 0.1 N [hydrochloric acid](#); 750 mL