



Bupropion Hydrochloride Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	27-Mar-2026
Official Date	1-Apr-2026
Expert Committee	Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Bupropion Hydrochloride Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 30* and *31* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). The revision also necessitates a change in the table numbering in the test for *Organic Impurities*. Existing references to reagents have been updated for consistency with the reagent entry. For additional information about reagent cross references, please see the related [Compendial Notice](#).

- *Dissolution Test 30* was validated using the Symmetry C8 brand of column with L7 packing. The typical retention time for bupropion is about 2.4 min.

The Bupropion Hydrochloride Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Tsion Billign, Principal Scientist (301-816-8286 or tb@usp.org).

Bupropion Hydrochloride Extended-Release Tablets

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](#).[▲] (RB 1-Apr-2026) 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 \times 10-cm; 3.5- μ m packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 5 μ L

System suitability

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

[NOTE—See [Table 32](#).[▲] (RB 1-Apr-2026) 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 solution*

Determine 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 solution*

Determine 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

Time (h)	Amount Dissolved (%)
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 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)	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):

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

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

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

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

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 solution*

Determine 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 solution*

Determine 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

Time (h)	Amount Dissolved (%)
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

Buffer stage medium: pH 6.8 phosphate buffer (add 250 mL of 76 g/L [tribasic sodium phosphate](#) to the *Acid stage medium*, adjust with [2 N hydrochloric acid TS](#) or [2 N sodium hydroxide TS](#) to a pH of 6.8, if necessary); 1000 mL

Apparatus 2: 50 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*.

Acid stage standard solution: 0.06 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*. Sonication may be used to aid in dissolution.

Buffer stage standard solution: 0.15 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Buffer stage medium*. Sonication may be used to aid in dissolution.

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: *Acid stage medium* or *Buffer stage medium*

Analysis

Samples: *Acid stage standard solution*, *Buffer stage 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 :

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

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

A_S = absorbance of bupropion hydrochloride from the *Acid stage standard solution* or *Buffer stage standard solution*

C_S = concentration of [USP Bupropion Hydrochloride RS](#) in the *Acid stage standard solution* or *Buffer stage 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):

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

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

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

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

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

V_A = volume of *Acid stage medium*, 750 mL

L = label claim (mg/Tablet)

V_B = volume of *Buffer stage medium*, 1000 mL

V_S = volume of *Sample solution* withdrawn from the *Acid stage medium* or *Buffer stage medium* (mL)

Tolerances: See [Table 14](#).

Table 14

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 10
2	3	10–30
3	8	55–85
4	16	NLT 75

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 12: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 12*.

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

Apparatus 1: 75 rpm

Times: 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

Sample solution: Withdraw at least 10 mL of the solution under test and pass through a suitable filter.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 252 nm

Cell

For Tablets labeled to contain 150 mg: 0.1 cm

For Tablets labeled to contain 300 mg: 0.05 cm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

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 :

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

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)

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

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

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

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

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

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 from the *Medium* (mL)

Tolerances: See [Table 15](#).

Table 15

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 25
2	4	25–50
3	8	60–85
4	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 13: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 13*.

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

Apparatus 1: 75 rpm

Times: 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

Sample solution: Withdraw at least 10 mL of the solution under test and centrifuge. Use the supernatant.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 252 nm

Cell: 0.1 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 concentration (C_i) of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) in the sample withdrawn from the vessel at time point i :

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

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)

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

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

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

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

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

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 from the *Medium* (mL)

Tolerances: See [Table 16](#).

Table 16

Time Point (<i>i</i>)	Time (h)	Amount Dissolved (150 mg/Tablet) (%)	Amount Dissolved (300 mg/ Tablet) (%)
1	2	NMT 25	NMT 25
2	4	30–55	25–45
3	8	65–90	60–80
4	12	NLT 80	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 14: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 14*.

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

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. If necessary, dilute the solution with *Medium*.

Sample solution: Pass a portion of the solution under test through a suitable filter. Replace the portion removed with the same volume of *Medium*. If necessary, dilute the filtrate with *Medium*.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 252 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 :

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

A_i = 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):

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

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 17](#).

Table 17

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 20
2	4	20–45
3	8	55–85
4	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 15: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 15*.

Acid stage

Acid stage medium: 0.1 N [hydrochloric acid](#), degassed; 900 mL

Apparatus 1: 100 rpm

Time: 2 h in *Acid stage medium*

Buffer: 3.5 g/L of [monobasic sodium phosphate](#) prepared as follows. Dissolve 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 2.8.

Mobile phase: [Methanol](#) and *Buffer* (45:55)

Acid stage standard solution: 0.033 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*. Sonication may be used to promote dissolution.

Acid stage sample solution: Pass a portion of the solution under test through a suitable filter, discard the first 5 mL, and use the filtrate. Then discard the Tablets and remaining solution.

[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 [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 1.5 times the retention time of bupropion

System suitability

Sample: *Acid stage standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Acid stage standard solution* and *Acid stage sample solution*

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

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

r_U = peak response of bupropion from the *Acid stage sample solution*

r_S = peak response of bupropion from the *Acid stage standard solution*

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

V = volume of *Acid stage medium*, 900 mL

L = label claim (mg/Tablet)

Buffer stage: Use fresh Tablets.

Buffer stage medium: pH 6.8 tribasic sodium phosphate buffer and 0.5% sodium lauryl sulfate (Dissolve 19 g of [tribasic sodium phosphate](#) in 1 L of [water](#), add 7 mL of [hydrochloric acid](#), and adjust with [0.2 N sodium hydroxide TS](#) or dilute [hydrochloric acid](#) to a pH of 6.8. Add 5 g of [sodium dodecyl sulfate](#). To promote dissolution, the resulting solution can be continuously stirred and heated to 41°. Allow the solution to cool to 37° before use. Do not allow the temperature to fall below 36.5° before beginning the test.); 900 mL

Apparatus 1: 100 rpm

Times: 1, 2, 4, and 8 h

Buffer: 1.4 g/L of [dibasic ammonium phosphate](#) and 0.5 g/L of [sodium 1-hexanesulfonate](#) prepared as follows. Dissolve 1.4 g of [dibasic ammonium phosphate](#) and 0.5 g of [sodium 1-hexanesulfonate](#) in 1 L of [water](#). To each 1 L of this solution, add 2.0 mL of [triethylamine](#), and adjust with [phosphoric acid](#) to a pH of 7.0.

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

Buffer stage standard solution: 0.33 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Buffer stage medium*

Buffer stage sample solution: Pass a portion of the solution under test through a suitable filter, discard the first 5 mL, and use the filtrate.

Chromatographic system: Proceed as directed under the *Acid stage*.

System suitability

Sample: *Buffer stage standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Buffer stage standard solution* and *Buffer stage 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 *Buffer stage sample solution* at time point i

r_S = peak response of bupropion from the *Buffer stage standard solution*

C_S = concentration of [USP Bupropion Hydrochloride RS](#) in the *Buffer stage 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):

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

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

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

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

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

V = volume of *Buffer stage medium*, 900 mL

L = label claim (mg/Tablet)

V_S = volume of *Buffer stage sample solution* withdrawn at each time point (mL)

Tolerances

Acid stage: NMT 10%; the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved at the time specified conforms to [Dissolution \(711\)](#), [Acceptance Table 3](#).

Buffer stage: See [Table 18](#).

Table 18

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	5–25

Time Point (<i>i</i>)	Time (h)	Amount Dissolved (%)
2	2	25–45
3	4	60–85
4	8	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](#).

Test 16: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 16*.

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

Apparatus 1: 75 rpm

Times: 2, 5, 8, and 16 h

Buffer: 3.5 g/L of [monobasic sodium phosphate](#) prepared as follows. Dissolve 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 2.8.

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

Standard solution: 0.17 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*. Sonication may be used to promote dissolution.

Sample solution: Pass a portion of the solution under test through a suitable filter, and discard NLT 1 mL. Dilute the filtrate with *Medium* if necessary. Replace the portion removed with the same volume of *Medium*. [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 [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 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*:

$$\text{Result}_i = (r_i/r_S) \times C_S \times D$$

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)

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):

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

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 19](#).

Table 19

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 10
2	5	30–60
3	8	65–88
4	16	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](#).

Test 18: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 18*.

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

Apparatus 1: 75 rpm

Times: 2, 4, 8, and 16 h

Buffer: 6.8 g/L of [monobasic potassium phosphate](#) in [water](#) (RB 1-Apr-2026) adjusted 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: Centrifuge a portion of the solution under test for 15 min.

Chromatographic system

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

Mode: LC

Detector: UV 298 nm

Column: 4.6-mm × 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):

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

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

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

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

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 20](#).

Time Point (i)	Time (h)	Amount Dissolved (for Tablets that contain 150 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain 300 mg of bupropion hydrochloride) (%)
1	2	NMT 20	NMT 20
2	4	25–50	25–50
3	8	65–95	60–85
4	16	NLT 80	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 20: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 20*.

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

Apparatus 1: 75 rpm

Times: 2, 4, 8, and 16 h

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

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

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 :

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

A_i = 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):

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

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 21](#).

Table 21

Time Point (i)	Time (h)	Amount Dissolved (for Tablets that contain 150 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain 300 mg of bupropion hydrochloride) (%)
1	2	NMT 15	NMT 15
2	4	10–35	10–35
3	8	55–80	50–75
4	16	NLT 80	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 21: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 21*.

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

Apparatus 1: 75 rpm

Times: 4, 8, and 16 h

Standard stock solution 1: 0.84 mg/mL of [USP Bupropion Hydrochloride RS](#) prepared as follows.

Transfer a suitable amount of [USP Bupropion Hydrochloride RS](#) to an appropriate volumetric flask. Add 50% of the flask volume of [acetonitrile](#). Dilute with [water](#) to volume.

Standard stock solution 2: 0.17 mg/mL of [USP Bupropion Hydrochloride RS](#) from *Standard stock solution 1* in *Medium*

Standard solution: 0.017 mg/mL of [USP Bupropion Hydrochloride RS](#) from *Standard stock solution 2* in *Medium* passed through a suitable filter of 0.45- μ m pore size

Sample solution: Dilute a portion of the solution under test with *Medium*. Pass a portion of the resulting solution through a suitable filter of 0.45- μ m pore size. Replace the portion removed with the same volume of *Medium*.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 252 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 :

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

A_i = 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):

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 22](#).

Table 22

Time Point (i)	Time (h)	Amount Dissolved (for Tablets that contain 150 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain 300 mg of bupropion hydrochloride) (%)
1	4	NMT 20	NMT 30
2	8	35–60	50–70
3	16	NLT 80	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 22: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 22*.

Acid stage medium: [0.1 N hydrochloric acid VS](#); 750 mL

Buffer stage medium: Sodium phosphate buffer, pH 6.8 (after 2 h, add 250 mL of 76 g/L of [tribasic sodium phosphate](#), previously heated to $37 \pm 0.5^\circ$, to the *Acid stage medium* and adjust with [2 N hydrochloric acid TS](#) or [2 N sodium hydroxide TS](#), if necessary, to a pH of 6.8); 1000 mL

Apparatus 2: 50 rpm

Times: 2 h in *Acid stage medium*; 4 and 12 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.

Acid stage standard solution: 0.08 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*

Buffer stage standard solution: 0.3 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Buffer stage medium*

Acid stage sample solution and Buffer stage sample solution: Use a portion of the solution under test.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 298 nm

Blank: *Acid stage medium* or *Buffer stage medium*

System suitability

Samples: *Acid stage standard solution* and *Buffer stage standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%, *Acid stage standard solution* and *Buffer stage standard solution*

Analysis

Samples: *Acid stage standard solution*, *Buffer stage standard solution*, *Acid stage sample solution*, and *Buffer stage 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 :

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

A_i = absorbance from the *Acid stage sample solution* or *Buffer stage sample solution* at time point i

A_S = absorbance from the *Acid stage standard solution* or *Buffer stage standard solution* at time point i

C_S = concentration of [USP Bupropion Hydrochloride RS](#) in the *Acid stage standard solution* or *Buffer stage standard solution* (mg/mL)

D = dilution factor, if needed

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved in *Acid stage medium*:

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

C_1 = concentration of bupropion hydrochloride in the portion of the sample withdrawn at time point 1

V_A = volume of *Acid stage medium*, 750 mL

L = label claim (mg/Tablet)

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

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

$$\text{Result}_3 = \{[C_3 \times (V_B - V_{SB} - V_{SA})] + (C_2 \times V_{SB}) + (C_1 \times V_{SA})\} \times (1/L) \times 100$$

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

V_B = volume of *Buffer stage medium*, 1000 mL

V_{SA} = volume of *Acid stage sample solution* withdrawn at time point 1 (mL)

L = label claim (mg/Tablet)

V_{SB} = volume of *Buffer stage sample solution* withdrawn at each time point (mL)

Tolerances: See [Table 23](#).

Table 23

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 15
2	4	40–60
3	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 23: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 23*.

Acid stage medium: [0.1 N hydrochloric acid VS](#); 900 mL, deaerated

Buffer stage medium: [pH 6.8 phosphate buffer](#); 900 mL, deaerated

Apparatus 1: 75 rpm

Times: 2 h in *Acid stage medium*; 6 and 16 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.

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

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

Acid stage sample solution and Buffer stage 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, flow cell

Blank: *Acid stage medium* or *Buffer stage medium*

System suitability

Samples: *Acid stage standard solution* and *Buffer stage standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%, *Acid stage standard solution* and *Buffer stage standard solution*

Analysis

Samples: *Acid stage standard solution*, *Buffer stage standard solution*, *Acid stage sample solution*, and *Buffer stage 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 :

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

A_i = absorbance from the *Acid stage sample solution* or *Buffer stage sample solution* at time point i

A_S = absorbance from the *Acid stage standard solution* or *Buffer stage standard solution* at time point i

C_S = concentration of [USP Bupropion Hydrochloride RS](#) in the *Acid stage standard solution* or *Buffer stage standard solution* (mg/mL)

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved in *Acid stage medium* (Q_A):

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

C_1 = concentration of bupropion hydrochloride in the portion of the sample withdrawn at time point 1

V_A = volume of *Acid stage medium*, 900 mL

L = label claim (mg/Tablet)

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

$$\text{Result}_2 = [C_2 \times V_B \times (1/L) \times 100] + Q_A$$

$$\text{Result}_3 = [C_3 \times V_B \times (1/L) \times 100] + Q_A$$

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

V_B = volume of *Buffer stage medium*, 900 mL

L = label claim (mg/Tablet)

Q_A = percentage of the labeled amount of bupropion hydrochloride dissolved in the *Acid stage medium*

Tolerances: See [Table 24](#).

Table 24

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 15
2	6	50–75
3	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 24: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 24*.

Acid stage medium: 0.1 N [hydrochloric acid](#); 900 mL, deaerated

Buffer stage medium: pH 6.8 phosphate buffer with 0.5 M sodium chloride (Dissolve 6.8 g of [monobasic potassium phosphate](#) and 0.9 g of [sodium hydroxide](#) in 1 L of [water](#). Adjust with 0.2 M [sodium hydroxide](#) or [phosphoric acid](#) to a pH of 6.8. Add 29.2 g of [sodium chloride](#).); 900 mL, deaerated

Apparatus 1: 50 rpm

Times

For Tablets labeled to contain 150 mg of bupropion hydrochloride: 2 h in *Acid stage medium*; 3, 5, 8, and 10 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.

For Tablets labeled to contain 300 mg of bupropion hydrochloride: 2 h in *Acid stage medium*; 3, 6, 10, and 16 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.

Acid stage standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*, where L is the label claim, in mg/Tablet. Sonicate to dissolve, if necessary. Pass the resulting solution through a suitable filter of 0.45- μ m pore size, discarding the first 1 mL of filtrate. Use the solution within 1 h.

Buffer stage standard solution: ($L/900$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Buffer stage medium*, where L is the label claim, in mg/Tablet. Sonicate to dissolve, if necessary. Pass the resulting solution through a suitable filter of 0.45- μ m pore size, discarding the first 1 mL of filtrate.

Acid stage sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, discarding the first 1 mL of filtrate. Use the solution within 3 h. Remove the remainder of the solution under test from the vessel and proceed with testing in *Buffer stage medium*.

Buffer stage sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, discarding the first 1 mL of filtrate. Replace the portion removed with the same volume of the *Buffer stage medium*.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 298 nm

Cell: 0.5 cm

Blank: *Acid stage medium* or *Buffer stage medium*

Analysis

Samples: *Acid stage standard solution*, *Buffer stage standard solution*, *Acid stage sample solution*, and *Buffer stage 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 :

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

A_U = absorbance from the *Acid stage sample solution* or *Buffer stage sample solution* at time point i

A_S = absorbance from the *Acid stage standard solution* or *Buffer stage standard solution* at time point i

C_S = concentration of [USP Bupropion Hydrochloride RS](#) in the *Acid stage standard solution* or *Buffer stage standard solution* (mg/mL)

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved in *Acid stage medium* (Q_A):

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

C_1 = concentration of bupropion hydrochloride in the portion of the sample withdrawn at time point 1

V_A = volume of *Acid stage medium*, 900 mL

L = label claim (mg/Tablet)

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

$$\text{Result}_2 = [C_2 \times V_B \times (1/L) \times 100] + Q_A$$

$$\text{Result}_3 = \{[(C_3 \times V_B) + (C_2 \times V_S)] \times (1/L) \times 100\} + Q_A$$

$$\text{Result}_4 = (\{(C_4 \times V_B) + [(C_3 + C_2) \times V_S]\} \times (1/L) \times 100) + Q_A$$

$$\text{Result}_5 = (\{(C_5 \times V_B) + [(C_4 + C_3 + C_2) \times V_S]\} \times (1/L) \times 100) + Q_A$$

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

V_B = volume of *Buffer stage medium*, 900 mL

L = label claim (mg/Tablet)

Q_A = percentage of the labeled amount of bupropion hydrochloride dissolved in the *Acid stage medium*

V_S = volume of *Sample solution* withdrawn at each time point and replaced with *Medium* (mL)

Tolerances: See [Table 25](#).

Table 25

Time Point (i)	For Tablets Labeled to Contain 150 mg of Bupropion Hydrochloride		For Tablets Labeled to Contain 300 mg of Bupropion Hydrochloride	
	Time (h)	Amount Dissolved (%)	Time (h)	Amount Dissolved (%)
1	2	NMT 10	2	NMT 10
2	3	11–31	3	5–25
3	5	41–61	6	29–49
4	8	64–84	10	58–78
5	10	NLT 80	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 25: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 25*.

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

Apparatus 1: 75 rpm

Times: 2, 4, 8, and 12 h

Standard stock solution: 0.33 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*. Sonication may be used to promote dissolution.

Standard solution: 0.033 mg/mL of [USP Bupropion Hydrochloride RS](#) from *Standard stock solution* in *Medium*

Sample solution: Dilute a portion of the solution under test with *Medium*. Pass a portion of the resulting solution through a suitable filter of 0.45- μ m pore size, discarding the first few milliliters of filtrate.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 252 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*

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

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

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

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

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

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 26](#).

Table 26

Time Point (i)	Time (h)	Amount Dissolved (for Tablets that contain 150 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets that contain 300 mg of bupropion hydrochloride) (%)
1	2	NMT 15	NMT 15
2	4	15–35	20–40
3	8	60–80	60–80
4	12	NLT 80	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 26: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 26*.

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

Apparatus 1: 75 rpm

Times: 2, 6, and 14 h

Standard stock solution: 0.17 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*. Sonication may be used to promote dissolution.

Standard solution: 0.017 mg/mL of [USP Bupropion Hydrochloride RS](#) from *Standard stock solution* in *Medium*

Sample solution: Dilute a portion of the solution under test with *Medium*. Pass a portion of the resulting solution through a suitable filter of 0.45- μm pore size, discarding the first few milliliters of filtrate. Replace the portion removed with the same volume of *Medium*.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 252 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of bupropion hydrochloride ($\text{C}_{13}\text{H}_{18}\text{ClNO} \cdot \text{HCl}$) 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*

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

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 27](#).

Table 27

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 20
2	6	40–65

Time Point (i)	Time (h)	Amount Dissolved (%)
3	14	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 27: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 27*.

Acid stage medium: 0.1 N [hydrochloric acid](#); 750 mL, deaerated

Buffer stage medium: pH 6.8 phosphate buffer (Add 250 mL of solution containing 76 g of [sodium phosphate, tribasic](#) (dodecahydrate) in 1 L [water](#) to the *Acid stage medium*, adjust with 2 N [sodium hydroxide](#) or 2 N [hydrochloric acid](#) to a pH of 6.8, if necessary.); 1000 mL

Apparatus 2: 50 rpm with suitable sinkers

Times: 2 h in *Acid stage medium*; 4 and 12 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.

Buffer: Dissolve 3.45 g of [sodium phosphate, monobasic](#) (monohydrate) in 1000 mL of [water](#). Discard 4.0 mL of the solution, then add 4.0 mL of [triethylamine](#) and adjust with [phosphoric acid](#) to a pH of 2.8.

Mobile phase: [Methanol](#) and *Buffer* (55:45)

Standard solution: ($L/1000$) mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*, where L is the label claim, in mg/Tablet. Sonicate to dissolve.

Acid stage sample solution: At the time specified, withdraw a 10-mL aliquot of the solution under test without replacing the withdrawn volume. Pass the withdrawn portion through a suitable filter of 10- μ m pore size.

Buffer stage sample solution: At the times specified, withdraw a 10-mL aliquot of the solution under test without replacing the withdrawn volume. Pass the withdrawn portions at each time point through a suitable filter of 10- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 298 nm

Column: 4.6-mm \times 15-cm; 5- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μ L

Run time: NLT 2.2 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, Acid stage sample solution, and Buffer stage 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 each time point (i):

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

r_U = peak response of bupropion from the *Acid stage sample solution* or *Buffer stage sample solution*

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

C_S = concentration of [USP Bupropion Hydrochloride RS](#) from 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):

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

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

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

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

V_A = volume of *Acid stage medium*, 750 mL

L = label claim (mg/Tablet)

V_B = volume of *Buffer stage medium*, 1000 mL

V_S = volume of *Acid stage sample solution* or *Buffer stage sample solution* withdrawn at each time point, 10 mL

Tolerances: See [Table 28](#).

Table 28

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 25
2	4	40–60
3	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 28: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 28*.

Acid stage medium: 0.1 N [hydrochloric acid](#); 750 mL, deaerated

Buffer stage medium: 0.05 M sodium phosphate buffer, pH 6.8 with 5 g/L of sodium dodecyl sulfate (Dissolve 38.3 g of [sodium phosphate, tribasic](#) (dodecahydrate) in 100 mL of [water](#) and transfer to a 2-L container containing 1800 mL of [water](#). Add 12.5 mL of [hydrochloric acid](#) and

adjust with [sodium hydroxide](#) or [hydrochloric acid](#) to a pH of 6.8. Dilute with [water](#) to volume. To each liter of this solution, add 5 g of [sodium dodecyl sulfate](#) and dissolve by stirring NLT 30 min.); 1000 mL, deaerated

Apparatus 1: 75 rpm

Times: 1 h in *Acid stage medium*; 4, 8, and 16 h in *Buffer stage medium*. The time in the *Buffer stage medium* includes the time in the *Acid stage medium*.

Acid stage standard solution: 0.04 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Acid stage medium*. Sonicate to dissolve.

Buffer stage standard solution: 0.15 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Buffer stage medium*. Sonicate to dissolve.

Acid stage sample solution: At the time specified, withdraw a 10-mL aliquot of the solution under test and pass the withdrawn portion through a suitable filter of 10- μ m pore size. Transfer the basket containing the Tablet to the vessel containing *Buffer stage medium* and proceed with testing in *Buffer stage medium*.

Buffer stage sample solution: At the times specified, withdraw a 10-mL aliquot of the solution under test without replacing the withdrawn volume. Pass the withdrawn portions at each time point through a suitable filter of 70- μ m pore size.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 252 nm

Cell: 0.1 cm

Blank: *Acid stage medium* or *Buffer stage medium*

Analysis

Samples: *Acid stage standard solution*, *Buffer stage standard solution*, *Acid stage sample solution*, and *Buffer stage 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 each time point (i):

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

A_U = absorbance from the *Acid stage sample solution* or *Buffer stage sample solution*

A_S = absorbance from the *Acid stage standard solution* or *Buffer stage standard solution*

C_S = concentration of [USP Bupropion Hydrochloride RS](#) in the *Acid stage standard solution* or *Buffer stage standard solution* (mg/mL)

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved in *Acid stage medium* (Q_A):

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

C_1 = concentration of bupropion hydrochloride in the portion of the sample withdrawn at time point 1 (mg/mL)

V_A = volume of *Acid stage medium*, 750 mL

L = label claim (mg/Tablet)

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

$$\text{Result}_2 = [C_2 \times V_B \times (1/L) \times 100] + Q_A$$

$$\text{Result}_3 = \{[C_3 \times (V_B - V_S)] + (C_2 \times V_S)\} \times (1/L) \times 100 + Q_A$$

$$\text{Result}_4 = \{[C_4 \times (V_B - 2 \times V_S)] + [(C_3 + C_2) \times V_S]\} \times (1/L) \times 100 + Q_A$$

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

V_B = volume of *Buffer stage medium*, 1000 mL

L = label claim (mg/Tablet)

Q_A = percentage of the labeled amount of bupropion hydrochloride dissolved in the *Acid stage medium*

V_S = volume of *Buffer stage sample solution* withdrawn at each time point, 10 mL

Tolerances: See [Table 29](#).

Table 29

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	NMT 10
2	4	27–52
3	8	57–82
4	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 30: If the product complies with this test, the labeling indicates that it meets [USP Dissolution Test 30](#).

Medium: 0.1 N [hydrochloric acid](#), pH 1.5 (Dissolve 3 g of [sodium hydroxide](#) in 1000 mL of [water](#) and sonicate to dissolve, if necessary. Add 8.5 mL of [hydrochloric acid](#) and mix. Adjust with either 0.1 N [hydrochloric acid](#) or 0.1 N [sodium hydroxide](#) to a pH of 1.5.); 900 mL, deaerated, if necessary

Apparatus 1: 50 rpm

Times: 1, 2, 4, and 8 h

Solution A: Dilute 20 mL of [phosphoric acid](#) with [water](#) to 100 mL and mix.

Buffer: Dissolve 6.8 g of [potassium phosphate, monobasic](#) in 1000 mL of [water](#) and sonicate to dissolve, if necessary. Adjust with *Solution A* to a pH of 3.0 ± 0.05 .

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

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

Sample solution: Withdraw a portion of the solution under test through a suitable filter of 10- μm pore size, and replace the portion removed with the same volume of *Medium*. Pass the withdrawn aliquot through a suitable filter of 0.45- μm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained. [NOTE—Protect the *Sample solution* from light.]

Chromatographic system

(See *Chromatography (621)*, *System Suitability*.)

Mode: LC

Detector: UV 298 nm

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

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 25 μL

Run time: NLT 2.1 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 ($\text{C}_{13}\text{H}_{18}\text{ClNO} \cdot \text{HCl}$) in the sample withdrawn from the vessel at each time point (i):

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

r_U = peak response of bupropion from the *Sample solution*

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 ($\text{C}_{13}\text{H}_{18}\text{ClNO} \cdot \text{HCl}$) dissolved at each time point (i):

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

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 30](#).

Table 30

Time Point (i)	Time (h)	Amount Dissolved (for Tablets labeled to contain 100 mg and 150 mg of bupropion hydrochloride) (%)	Amount Dissolved (for Tablets labeled to contain 200 mg of bupropion hydrochloride) (%)
1	1	20–40	20–40
2	2	35–55	35–55
3	4	60–80	55–75
4	8	NLT 80	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 31: If the product complies with this test, the labeling indicates that it meets USP [Dissolution Test 31](#).

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 75 rpm

Times

For Tablets labeled to contain 150 mg of bupropion hydrochloride: 2, 4, 8, and 12 h

For Tablets labeled to contain 300 mg of bupropion hydrochloride: 2, 4, 8, and 16 h

Standard solution: 0.0167 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Medium*

Sample solution: Withdraw a portion of the solution under test and replace the portion removed with the same volume of *Medium*. Pass the withdrawn aliquot at each time point through a suitable filter of 0.45- μ m pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained. Dilute the filtrate with *Medium* to a concentration similar to the *Standard solution*.

Instrumental conditions

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

Mode: UV-Vis

Analytical wavelength: 252 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 each time point (i):

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

A_U = absorbance response of bupropion from the *Sample solution*

A_S = absorbance response of bupropion from the *Standard solution*

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

D = dilution factor of the *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):

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

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

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

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

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 and replaced with *Medium* (mL)

Tolerances: See [Table 31](#).

Table 31

Time Point (i)	For Tablets labeled to contain 150 mg of bupropion hydrochloride		For Tablets labeled to contain 300 mg of bupropion hydrochloride	
	Time (h)	Amount Dissolved (%)	Time (h)	Amount Dissolved (%)
1	2	NMT 15	2	NMT 15
2	4	20–45	4	15–40
3	8	65–90	8	50–75
4	12	NLT 80	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](#). ▲ (RB 1-Apr-2026)

- **UNIFORMITY OF DOSAGE UNITS** (905): Meet the requirements

IMPURITIES

Change to read:

- **ORGANIC IMPURITIES**

Diluent 1, Solution A, Solution B, Mobile phase, and either **Sample stock solution A** and **Sample solution A** or **Buffer, Diluent 2, Sample stock solution B**, and **Sample solution B**: Proceed as directed in the Assay.

System suitability stock solution A: 0.02 mg/mL of [USP Bupropion Related Compound C RS](#), 0.02 mg/mL of [USP Bupropion Related Compound F RS](#), and 0.012 mg/mL of [USP 3-Chlorobenzoic Acid RS](#) in [methanol](#)

System suitability solution A: 0.002 mg/mL of bupropion related compound C, 0.002 mg/mL of bupropion related compound F, and 0.0012 mg/mL of 3-chlorobenzoic acid from *System suitability stock solution A* in *Diluent 1*

System suitability stock solution B: 0.012 mg/mL of [USP 3-Chlorobenzoic Acid RS](#) in [methanol](#)

System suitability solution B: 0.0012 mg/mL of 3-chlorobenzoic acid from *System suitability stock solution B* in *Diluent 1*

Standard solution: 0.0012 mg/mL of [USP Bupropion Hydrochloride RS](#) in *Diluent 1*

Sensitivity solution: 0.0006 mg/mL of [USP Bupropion Hydrochloride RS](#) from *Standard solution* in *Diluent 1*

Chromatographic system: Proceed as directed in the Assay except use a *Detector* as follows.

Detector: UV 226 nm, adjusted ± 2 nm so that the relative response factor requirement is met. [NOTE—The peak responses of the compounds of interest are very sensitive to changes in the detection wavelength.]

System suitability

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

[NOTE—See [Table 32](#) (RB 1-Apr-2026) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.3 between bupropion related compound F and bupropion related compound C, *System suitability solution A*; NLT 1.3 between bupropion related compound C and 3-chlorobenzoic acid, *System suitability solution A*

Relative standard deviation: NMT 10%, *Standard solution*

Relative response factor: 3.8–4.5 for the peak response of 3-chlorobenzoic acid in *System suitability solution B* divided by the peak response from bupropion in the *Standard solution*

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

Analysis

Samples: *System suitability solution B*, *Standard solution*, and *Sample solution A* or *Sample solution B*

Calculate the percentage of 3-chlorobenzoic acid in the portion of Tablets taken:

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

r_U = peak response of 3-chlorobenzoic acid from *Sample solution A* or *Sample solution B*

r_S = peak response of 3-chlorobenzoic acid from *System suitability solution B*

C_S = concentration of [USP 3-Chlorobenzoic Acid RS](#) in *System suitability solution B* (mg/mL)

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

Calculate the percentage of each other degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each other degradation product 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)

F = relative response factor for each other degradation product (see [Table 32](#) (RB 1-Apr-2026))

Acceptance criteria: See [Table 32](#) (RB 1-Apr-2026) The reporting threshold is 0.10%.

Table 32 (RB 1-Apr-2026)

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)	
			100 mg or less	150 mg or greater
Bupropion amine ^a	0.38	1.2	0.3	0.3
<i>S,S,S</i> -Thiomorpholine derivative ^b	0.56	1.1	1.0	1.5
<i>S,R,R</i> -Thiomorpholine derivative ^c	0.78	1.1	0.5	0.4
Bupropion	1.0	—	—	—
Bupropion related compound F	1.71	1.8	1.2	2.3
Bupropion related compound C	1.75	1.7	0.3	0.3
3-Chlorobenzoic acid	1.80	—	0.5	0.5
Bupropion dione derivative ^d	2.25	1.00	0.4	0.4
Any unspecified degradation product	—	1.00	0.2	0.2
Total impurities	—	—	3.2	3.3

^a 2-Amino-1-(3-chlorophenyl)-1-propanone.

^b (3*S*,5*S*,6*S*)-6-(3-Chlorophenyl)-6-hydroxy-5-methyl-3-thiomorpholine carboxylic acid.

^c (3*S*,5*R*,6*R*)-6-(3-Chlorophenyl)-6-hydroxy-5-methyl-3-thiomorpholine carboxylic acid.

^d 1-(3-Chlorophenyl)propane-1,2-dione.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature. Protect from light.
- **LABELING:** The labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** (11)

[USP Bupropion Hydrochloride RS](#)

[USP Bupropion Related Compound C RS](#)

[NOTE—May also be labeled as [USP Bupropion Hydrochloride Related Compound C RS](#).]

1-(3-Chlorophenyl)-2-hydroxypropan-1-one.

$C_9H_9O_2Cl$ 184.62

[USP Bupropion Related Compound F RS](#)

[NOTE—May also be labeled as [USP Bupropion Hydrochloride Related Compound F RS](#).]

1-(3-Chlorophenyl)-1-hydroxypropan-2-one.

$C_9H_9O_2Cl$ 184.62

[USP 3-Chlorobenzoic Acid RS](#)

3-Chlorobenzoic acid.

$C_7H_5ClO_2$ 156.57

Page Information:

Not Applicable

Current DocID:

© 2026 The United States Pharmacopeial Convention *All Rights Reserved*.