

Metoprolol Succinate Extended-Release Tablets

Type of Posting	Notice of Intent to Revise
Posting Date	27-Dec-2019
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Expert Committee	Chemical Medicines Monographs 2

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts and the [Pending Monograph Guideline](#), this is to provide notice that the Chemical Medicines Monographs 2 Expert Committee intends to revise the Metoprolol Succinate Extended-Release Tablets monograph.

Based on the supporting data received from a manufacturer awaiting FDA approval, the Expert Committee proposes to add *Dissolution Test 6*. The revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

- The analytical procedure in *Dissolution Test 6* was validated using a Zorbax SB C8 brand of L7 column from Agilent. The typical retention time for metoprolol succinate is about 2.2 min.

The proposed revision is contingent on FDA approval of a product that meets the proposed monograph specifications. The proposed revision will be published as a Revision Bulletin and an official date will be assigned to coincide as closely as possible with the FDA approval of the associated product.

See below for additional information about the proposed text.¹

Should you have any questions, please contact Donald Min, Senior Scientific Liaison to the Chemical Medicines Monographs 2 Expert Committee (301-230-7457 or ddm@usp.org).

¹ This text is not the official version of a *USP–NF* monograph and may not reflect the full and accurate contents of the currently official monograph. Please refer to the current edition of the *USP–NF* for official text.

USP provides this text to indicate changes that we anticipate will be made official once the product subject to this proposed revision under the Pending Monograph Program receives FDA approval. Once FDA approval is granted for the associated revision request, a Revision Bulletin will be posted that will include the changes indicated herein, as well as any changes indicated in the product's final approval, combined with the text of the monograph as effective on the date of approval. Any revisions made to a monograph under the Pending Monograph Program that are posted without prior publication for comment in the *Pharmacopeial Forum* must also meet the requirements outlined in the [USP Guideline on Use of Accelerated Processes for Revisions to the USP–NF](#).

Metoprolol Succinate Extended-Release Tablets

DEFINITION

Metoprolol Succinate Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$.

IDENTIFICATION

Change to read:

- A. Δ SPECTROSCOPIC IDENTIFICATION TESTS** <197>, *Infrared Spectroscopy*: 197K Δ (CN 1-May-2020)
Sample solution: Equivalent to 200 mg of metoprolol succinate from NLT 1 Tablet in a stoppered centrifuge tube. Add 40 mL of pH 6.8 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*) and 40 mL of methylene chloride, and shake for 5 min. Centrifuge, filter, and use the aqueous phase as the *Sample solution*.
Sample: Transfer 3 mL of the *Sample solution* to a separator. Add 2 mL of ammonium hydroxide, and extract with 20 mL of methylene chloride. Filter the methylene chloride phase. Grind 1 mL of the filtrate with 300 mg of potassium bromide, dry in a current of warm air, and prepare a disk.
Acceptance criteria: The IR spectrum of the *Sample* exhibits maxima only at the same wavelengths as those obtained from a similar preparation of USP Metoprolol Succinate RS (presence of metoprolol).

Change to read:

- B. Δ SPECTROSCOPIC IDENTIFICATION TESTS** <197>, *Infrared Spectroscopy*: 197K Δ (CN 1-May-2020)
Sample: Transfer 5 mL of the *Sample solution* prepared in *Identification A* to a glass-stoppered test tube. Add 2 mL of 5 N hydrochloric acid, and extract with 5 mL of ether. Filter the ether phase. Grind 2 mL of the filtrate with 300 mg of potassium bromide, dry in a current of warm air, and prepare a disk.
Acceptance criteria: The IR spectrum of the *Sample* exhibits maxima only at the same wavelengths as those obtained from a similar preparation of succinic acid (presence of succinate).
- C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

PROCEDURE

Buffer: Mix 50 mL of 1 M monobasic sodium phosphate and 8.0 mL of 1 M phosphoric acid, and dilute with water to 1000 mL. If necessary, adjust with 1 M monobasic potassium phosphate or 1 M phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (250:750)

Standard solution: 0.05 mg/mL of USP Metoprolol Succinate RS in *Mobile phase*

Sample stock solution: Nominally 1 mg/mL of metoprolol succinate prepared as follows. Transfer a suitable number of Tablets to a suitable volumetric flask, add about 5 mL of water, and allow the Tablets to disintegrate. Add a volume of alcohol to fill 30% of the flask volume, and shake for 30 min. Add a portion of 0.1 N hydrochloric acid to fill 50% of the flask volume, and shake for an additional 30 min. Dilute with 0.1 N hydrochloric acid to volume. Filter, and discard the first 10 mL of the filtrate.

Sample solution: Nominally 0.05 mg/mL of metoprolol succinate from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4-mm \times 12.5-cm; 5- μ m packing L7

Flow rate: 1 mL/min

Injection volume: 40 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ in the portion of Tablets taken:

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

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

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

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

C_U = nominal concentration of metoprolol succinate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

DISSOLUTION <711>

Test 1

Medium: pH 6.8 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 500 mL

Apparatus 2: 50 rpm

Times: 1, 4, 8, and 20 h

Buffer, Mobile phase, and Standard solution: Prepare as directed in the *Assay*.

Analysis: Proceed as directed in the *Assay*, except use 5.0 mL of a filtered portion of the solution under test as the *Sample solution*, and use *Medium* as the blank, in comparison with a *Standard solution* with a known concentration of USP Metoprolol Succinate RS in the same *Medium*.

Acceptance criteria: See *Table 1*.

Table 1

Time (h)	Amount Dissolved (%)
1	NMT 25
4	20–40
8	40–60
20	NLT 80

The percentages of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ 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 the product meets USP *Dissolution Test 2*.

Medium: Simulated gastric fluid without enzyme, pH 1.2; 500 mL

Apparatus 2: 75 rpm

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Times: 1, 4, 8, and 20 h

Buffer: 1 M monobasic sodium phosphate, 1 M phosphoric acid, and water (50:8:942). If necessary, adjust with 1 M monobasic sodium phosphate or 1 M phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (250:750)

Standard solution: Prepare a solution of USP Metoprolol Succinate RS in *Medium* as directed in *Table 2*.

Table 2

Tablet Strength (mg, as metoprolol succinate)	Concentration (mg/mL)
200	0.380
100	0.190
50	0.095
25	0.048

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

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.0-mm × 12.5-cm; 4-μm packing L7

Flow rate: 1 mL/min

Injection volume: See *Table 3*.

Table 3

Tablet Strength (mg, as metoprolol succinate)	Volume (μL)
25	40
50	20
100	10
200	5

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of metoprolol succinate dissolved in *Medium* at each time point (i):

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

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

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

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

Calculate the percentage of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ dissolved (Q_i), 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 metoprolol succinate in the portion of sample withdrawn at time point (i) (mg/mL)

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

V_S = volume of the *Sample solution* withdrawn from the *Medium* (mL)

Tolerances: See *Table 4*.

Table 4

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	NMT 20
2	4	20–40
3	8	55–85
4	20	NLT 80

The percentages of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ dissolved at the times specified conform to *Dissolution* <711>, *Acceptance Table 2*.

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

Medium: Phosphate buffer, pH 6.8 (dissolve 6.8 g of monobasic potassium phosphate and 0.93 g of sodium hydroxide in 1 L of water; adjust with sodium hydroxide to a pH of 6.8); 500 mL

Apparatus 2: 50 rpm

Times: 1, 4, 8, and 24 h

Buffer: 5.0 mL/L of triethylamine in water. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Methanol and *Buffer* (40:60)

Standard solution: Prepare a solution of USP Metoprolol Succinate RS in *Medium* as directed in *Table 5*.

Table 5

Tablet Strength (mg)	Concentration (mg/mL)
200	0.4
100	0.2
50	0.1
25	0.05

Sample solution: Withdraw a 10-mL aliquot at each time point. Pass the solution under test through a suitable filter of 0.45-μm pore size. Replace the portion withdrawn with an equal volume of *Medium*.

Chromatographic system

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

Mode: LC

Detector: UV 223 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 5 μL

Run time: NLT 2 times the retention time of metoprolol

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 metoprolol succinate dissolved in *Medium* at each time point (i):

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

- r_U = peak response of metoprolol from the *Sample solution*
- r_S = peak response of metoprolol from the *Standard solution*
- C_S = concentration of USP Metoprolol Succinate RS in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ dissolved (Q_i), at each time point (i):

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

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

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

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

- C_i = concentration of metoprolol succinate in the portion of sample withdrawn at time point (i) (mg/mL)
- V = volume of *Medium*, 500 mL
- L = label claim (mg/Tablet)
- V_S = volume of the *Sample solution* withdrawn from the *Medium* (mL)

Tolerances: See *Table 6*.

Table 6

Time Point (i)	Time (h)	Amount Dissolved (Tablet labeled 25 mg) (%)	Amount Dissolved (Tablets labeled 50, 100, and 200 mg) (%)
1	1	NMT 20	NMT 20
2	4	20–40	15–35
3	8	42–67	38–64
4	24	NLT 80	NLT 80

The percentages of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ 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 the product meets USP *Dissolution Test 5*.

Medium: Phosphate buffer, pH 6.8 (dissolve 27.22 g of monobasic potassium phosphate and 3.6 g of sodium hydroxide in 4 L of water; adjust with 1 N sodium hydroxide or phosphoric acid to a pH of 6.8); 500 mL

Apparatus 2: 50 rpm, with sinkers

Times: 1, 4, 8, and 20 h

Buffer: Transfer 3.0 mL of triethylamine and 1.0 mL of phosphoric acid to a 1000-mL volumetric flask that contains 600 mL of water. Dilute with water to volume.

Mobile phase: Acetonitrile and *Buffer* (25:75)

Standard solution: Prepare a solution of USP Metoprolol Succinate RS in *Medium* as directed in *Table 7*.

Table 7

Tablet Strength (mg)	Concentration (mg/mL)
200	0.2
100	0.2
50	0.05
25	0.05

Sample solution: Withdraw a 10-mL aliquot at each time point. Pass the solution under test through a suitable filter of 0.45- μ m pore size. Replace the portion withdrawn with an equal volume of *Medium*.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm \times 15-cm; 5- μ m packing L7

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 40 μ L for 25 and 50 mg; 10 μ L for 100 and 200 mg

Run time: NLT 2 times the retention time of metoprolol

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of metoprolol succinate dissolved in *Medium* at each time point (i):

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

- r_U = peak response of metoprolol from the *Sample solution*
- r_S = peak response of metoprolol from the *Standard solution*
- C_S = concentration of USP Metoprolol Succinate RS in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ dissolved (Q_i), at each time point (i):

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

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

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

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

- C_i = concentration of metoprolol succinate in the portion of sample withdrawn at time point (i) (mg/mL)
- V = volume of *Medium*, 500 mL
- L = label claim (mg/Tablet)
- V_S = volume of the *Sample solution* withdrawn from the *Medium* (mL)

Tolerances: See *Table 8*.

Table 8

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	NMT 10
2	4	5–30

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Table 8 (continued)

Time Point (i)	Time (h)	Amount Dissolved (%)
3	8	30–55
4	20	NLT 75

The percentages of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ 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 the product meets USP *Dissolution Test 6*.

Medium: Phosphate buffer, pH 6.8 (dissolve 6.805 g of monobasic potassium phosphate and 0.91 g of sodium hydroxide in 1 L of water; adjust with sodium hydroxide or phosphoric acid to a pH of 6.8); 500 mL

Apparatus 2: 50 rpm

Times: 1, 4, 8, and 20 h

Solution A: 121.2 g/L of monobasic sodium phosphate in water

Solution B: Dilute 50 mL of *Solution A* and 8 mL of 1 M phosphoric acid with water to 1000 mL. Adjust with *Solution A* to a pH of 3.0.

Mobile phase: Acetonitrile and *Solution B* (25:75)

Standard solution: Prepare a solution of USP Metoprolol Succinate RS in *Medium* as directed in *Table 9*.

Table 9

Tablet Strength (mg)	Concentration (mg/mL)
100	0.2
200	0.4

Sample solution: Withdraw a 5-mL aliquot at each time point. Pass the solution under test through a suitable filter of 10- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm \times 10-cm; 3.5- μ m packing L7

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μ L

Run time: NLT 2.5 times the retention time of metoprolol

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 metoprolol succinate dissolved in *Medium* at each time point (i):

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

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

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

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

Calculate the percentage of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ dissolved (Q_i), at each time point (i):

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

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

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

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

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

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

V_S = volume of the *Sample solution* withdrawn from the *Medium* (mL)

Tolerances: See *Table 10*.

Table 10

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	NMT 20
2	4	12–32
3	8	38–58
4	20	NLT 80

The percentages of the labeled amount of metoprolol succinate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_4]$ dissolved at the times specified conform to *Dissolution* <711>, *Acceptance Table 2*. ▲ (TBD)

- **UNIFORMITY OF DOSAGE UNITS** <905>: Meet the requirements

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Buffer: 1.15 mL of phosphoric acid in 2 L of water. Add 2.6 g of sodium dodecyl sulfate. Sonicate to dissolve.

Solution A: Methanol and *Buffer* (30:70)

Solution B: Acetonitrile and *Buffer* (75:25)

Mobile phase: See ▲ *Table 11*.

Table 11 ▲ (TBD)

Time (min)	Solution A (%)	Solution B (%)
0	65	35
20	65	35
25	40	60
30	35	65
35	35	65
37	65	35
50	65	35

Diluent: Acetonitrile and *Buffer* (40:60)

System suitability solution: 3 μ g/mL of USP Metoprolol Related Compound A RS and 1 mg/mL of USP Metoprolol Succinate RS in *Diluent*

Standard solution: 3 μ g/mL of USP Metoprolol Succinate RS in *Diluent*

Sensitivity solution: 0.5 μ g/mL of USP Metoprolol Succinate RS from *Standard solution* in *Diluent*

Sample solution: Nominally 1 mg/mL of metoprolol succinate from Tablets prepared as follows. Transfer a portion of finely powdered Tablets (NLT 20), equivalent to 50 mg of metoprolol succinate, to a 50-mL volumetric flask. Add *Diluent* to fill 60% of the flask volume and sonicate for 30 min with intermittent shaking. Dilute with *Diluent* to volume. Pass the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 223 nm

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

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between metoprolol related compound A and metoprolol, *System suitability solution*
Relative standard deviation: NMT 5.0%, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response of each unspecified degradation product from the *Sample solution*

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

C_S = concentration of USP Metoprolol Succinate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of metoprolol succinate in the *Sample solution* (µg/mL)

Acceptance criteria: See **Table 12.** (TBD) Reporting threshold: 0.05%.

Table 12. (TBD)

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Succinic acid ^a	0.1	—
Metoprolol related compound A	0.83	—
Metoprolol	1.0	—
Any unspecified degradation product	—	0.20
Total impurities	—	0.75

^a Counter ion included for identification only.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.
- **LABELING:** Label it to indicate the content of metoprolol succinate and its equivalent, expressed as metoprolol succinate [(C₁₅H₂₅NO₃)₂ · C₄H₆O₆]. When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** (11)
 USP Metoprolol Related Compound A RS
 1-Ethylamino-3-[4-(2-methoxyethyl)phenoxy]propan-2-ol.
 C₁₄H₂₃NO₃ 253.34
 USP Metoprolol Succinate RS