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Bromocriptine Mesylate Tablets

DEFINITION

Bromocriptine Mesylate Tablets contain bromocriptine mesylate ($C_{32}H_{40}BrN_5O_5 \cdot CH_4SO_3$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of bromocriptine ($C_{32}H_{40}BrN_5O_5$).

IDENTIFICATION

• **A.** The principal spot of the *Sample solution* corresponds, in R_f value and color, to that of the *Standard stock solution*, as obtained in the test for *Organic Impurities*.

ASSAY

PROCEDURE

Buffer: 0.01 M ammonium carbonate in water

Mobile phase: Acetonitrile and *Buffer* (65:35)

Standard solution: 0.22 mg/mL of [USP Bromocriptine Mesylate RS](#) in methanol

Sample solution: Transfer a quantity of powdered Tablets (NLT 20), equivalent to 10 mg of bromocriptine, to an appropriate container. Add 40 mL of methanol, and stir for 20 min, protected from light. Quantitatively filter through a fine glass filtering funnel into a 50-mL volumetric flask. Rinse the filter with methanol, adding the rinsing to the filtrate, and dilute with methanol to volume.

Chromatographic system

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

Mode: LC

Detector: UV 300 nm

Column: 4-mm × 25-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Coefficient of variation: NMT 3.0% for 3 replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bromocriptine ($C_{32}H_{40}BrN_5O_5$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of bromocriptine, 654.59

M_{r2} = molecular weight of bromocriptine mesylate, 750.70

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

DISSOLUTION (711)

Test 1: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 1: 120 rpm

Time: 60 min

Standard solution: [USP Bromocriptine Mesylate RS](#) at a known concentration in *Medium*

[NOTE—A volume of alcohol not to exceed 5% of the total volume of the *Standard solution* may be used to dissolve the Standard before dilution with *Medium*.]

Sample solution: Sample per [Dissolution \(711\)](#), passed through a glass-fiber filter.

Blank: *Medium*

Instrumental conditions

(See [Fluorescence Spectroscopy \(853\)](#).)

Mode: Fluorometry

Excitation wavelength: 315 nm

Emission wavelength: 445 nm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of the labeled amount of bromocriptine ($C_{32}H_{40}BrN_5O_5$) dissolved.

Tolerances: NLT 80% (Q) of the labeled amount of bromocriptine ($C_{32}H_{40}BrN_5O_5$) is dissolved.

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; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: 0.01 M ammonium carbonate in water

Mobile phase: Acetonitrile and *Buffer* (65:35)

Standard solution: Dissolve [USP Bromocriptine Mesylate RS](#) in methanol, and quantitatively dilute with *Medium* to obtain a solution having a known concentration similar to the expected concentration of the *Sample solution*.

Sample solution: Sample per [Dissolution \(711\)](#).

Chromatographic system

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

Mode: LC

Detector: UV 300 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 100 µL

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 bromocriptine ($C_{32}H_{40}BrN_5O_5$) dissolved.

Tolerances: NLT 80% (Q) of the labeled amount of bromocriptine ($C_{32}H_{40}BrN_5O_5$) is dissolved.

Change to read:

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

[NOTE—Protect all solutions from light.]

Diluent: Dissolve 1.0 g of tartaric acid in 500 mL of water, add 500 mL of methanol, and mix.

Standard solution: 0.04 mg/mL of [USP Bromocriptine Mesylate RS](#) in *Diluent*

Sample solution: Transfer 1 Tablet into a 25-mL volumetric flask. Add 15 mL of *Diluent*, and shake by mechanical means for 30 min. Dilute with *Diluent* to volume, and mix. Filter, and dilute 10.0 mL of the clear filtrate with *Diluent* to 50.0 mL.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 306 nm

Cell: 1 cm

Blank: *Diluent*

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of the labeled amount of bromocriptine ($C_{32}H_{40}BrN_5O_5$) in the Tablet taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*