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Metyrosine Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-metyrosine-caps-20200921.

DEFINITION
Metyrosine Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of metyrosine ($C_{10}H_{13}NO_3$).

IDENTIFICATION

• **A. Ultraviolet Absorption**

Sample solution: 0.1 mg/mL solution of the Capsule contents in dilute hydrochloric acid (1 in 100)

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Metyrosine RS, concomitantly measured.

ASSAY

• **Procedure**

Diluent: Dilute hydrochloric acid (1 in 100)

Standard solution: 100 µg/mL of USP Metyrosine RS in *Diluent*

Sample stock solution: Combine the contents of Capsules (NLT 20), and transfer the nominal equivalent of 100 mg of metyrosine to a 100-mL volumetric flask. Add 50 mL of *Diluent*, shake by mechanical means for 45 min, dilute with *Diluent* to volume, and filter.

Sample solution: Nominally 0.1 mg/mL of metyrosine, from *Sample stock solution*, in *Diluent*

Spectrometric conditions

Mode: UV

Analytical wavelength: Maximum at about 274 nm

Blank: Dilute hydrochloric acid solution (1 in 100)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of metyrosine ($C_{10}H_{13}NO_3$) in the portion of Capsules taken:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

▲Test 1▲ (RB 22-Sep-2020)

Medium: 0.1 N hydrochloric acid; 750 mL

Apparatus 1: 100 rpm

Time: 60 min

Standard solution: USP Metyrosine RS at a known concentration in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* as needed.

Spectrometric conditions

Mode: UV

Analytical wavelength: Maximum at about 274 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: NLT 75% (*Q*) of the labeled amount of metyrosine ($C_{10}H_{13}NO_3$) is dissolved.

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

Tier 1

Medium: 0.1 N hydrochloric acid (degassed); 750 mL

Apparatus 1: 100 rpm. A 20-mesh basket may be used.

Time: 30 min

Tier 2

Medium: Transfer 15.09 ± 0.1 g of pepsin (Activity: 371 units/mg) into a suitable container with about 8000 mL of degassed 0.1 N hydrochloric acid. Stir gently to dissolve it and mix well. (Final activity of pepsin in *Medium* is about 700000 units/L); 750 mL

Apparatus 1: 100 rpm. A 20-mesh basket may be used

Time: 30 min

Standard solution: 0.33 mg/mL of USP Metyrosine RS prepared as follows. Transfer an appropriate amount of USP Metyrosine RS into a suitable volumetric flask. Add methanol to 2%–3% of the flask volume and sonicate to disperse. Add *Medium* to about 70% of the flask volume, and sonicate to dissolve. Dilute with *Medium* to volume. [NOTE—*Medium* in *Tier 1* or *Tier 2* should be used respectively.]

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 274 nm

Path length: 0.2-cm

Blank: *Medium*. [NOTE—*Medium* in *Tier 1* or *Tier 2* should be used respectively.]

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Perform the test using the conditions in *Tier 1*. Perform the *Tier 2* test only if the *Tolerances* in *Tier 1* can not be met because of the presence of cross-linking in the gelatin. Repeat the test with new Capsules using the conditions in *Tier 2*.

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of metyrosine ($C_{10}H_{13}NO_3$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

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

V = volume of *Medium*, 750 mL

L = label claim (mg/Capsule)

Tolerances: NLT 80% (*Q*) of the labeled amount of metyrosine ($C_{10}H_{13}NO_3$) is dissolved.▲ (RB 22-Sep-2020)

• **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Add the following:

▲• **LABELING:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.▲ (RB 22-Sep-2020)

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Metyrosine RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METYROSINE CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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