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Methyldopa Tablets

DEFINITION

Methyldopa Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of methyldopa ($C_{10}H_{13}NO_4$).

IDENTIFICATION

- **A.**

  Analysis: To about 10 mg of finely ground Tablets add 3 drops of a solution of ninhydrin in sulfuric acid (1 in 250).

  Acceptance criteria: A dark purple color is produced within 5–10 min that changes to pale brownish yellow on addition of 3 drops of water.

- **B.**

  Analysis: To about 10 mg of finely ground Tablets add 2 mL of 0.1 N sulfuric acid and 2 mL of *Solution A*, prepared as directed in the *Assay*, followed by 0.25 mL of 6 N ammonium hydroxide.

  Acceptance criteria: A dark purple color is produced immediately.

ASSAY

- **Procedure**

  Solution A: Freshly dissolve 1 g of ferrous sulfate, 2 g of potassium sodium tartrate, and 100 mg of sodium bisulfite in water to make a 100-mL solution.

  Solution B: 50 g/L of ammonium acetate in 20% alcohol. Adjust with 6 N ammonium hydroxide to a pH of 8.5.

  Standard solution: 1 mg/mL of anhydrous methyldopa from USP Methyldopa RS in 0.1 N sulfuric acid

  Sample solution: Nominally 1 mg/mL of methyldopa in 0.1 N sulfuric acid from NLT 20 powdered Tablets prepared as follows. To a 100-mL volumetric flask add 0.1 N sulfuric acid to fill about 50% of the volume of the flask, agitate by mechanical means for 15 min, and then dilute with 0.1 N sulfuric acid to volume. Filter the solution, and reject the first 20 mL of the filtrate.

  Blank: Water

  Instrumental conditions

  Mode: UV-Vis

  Analytical wavelength: 520 nm

  Cell: 1 cm

  Analysis

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

  Pipet 5 mL each of *Standard solution*, *Sample solution*, and *Blank* into separate 100-mL volumetric flasks. Add to each flask 5 mL of *Solution A*, and dilute with *Solution B* to volume.

  Calculate the percentage of the labeled amount of methyldopa ($C_{10}H_{13}NO_4$) in the portion of Tablets 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 Methyldopa RS in the *Standard solution* (mg/mL)

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

  Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **Dissolution** ⟨711⟩

  Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Instrumental conditions

Mode: UV

Analytical wavelength: 280 nm

Standard solution: USP Methyldopa RS in *Medium*

Sample solution: Sample per *Dissolution* ⟨711⟩. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Analysis: Determine the amount of methyldopa ($C_{10}H_{13}NO_4$) dissolved.

Tolerances: NLT 80% (*Q*) of the labeled amount of methyldopa ($C_{10}H_{13}NO_4$) is dissolved.

- **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩
  USP Methyldopa RS

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

Topic/Question	Contact	Expert Committee
METHYLDOPA TABLETS	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

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