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Diethylcarbamazine Citrate Tablets

DEFINITION

Diethylcarbamazine Citrate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of diethylcarbamazine citrate ($C_{10}H_{21}N_3O \cdot C_6H_8O_7$).

[NOTE—Diethylcarbamazine Citrate Tablets labeled solely for veterinary use are exempt from the requirements of the test for *Dissolution*.]

IDENTIFICATION

• **A. IDENTIFICATION—ORGANIC NITROGENOUS BASES ⟨181⟩:** Meet the requirements

ASSAY

• **PROCEDURE**

Solution A: 10 g/L of monobasic potassium phosphate in water

Solution B: 31.24 mg/mL of monobasic potassium phosphate in water

Mobile phase: Methanol and *Solution A* (100:900)

Standard solution: 0.1 mg/mL of USP Diethylcarbamazine Citrate RS in *Solution B*

Sample solution: Nominally 0.1 mg/mL of diethylcarbamazine citrate prepared as follows. Transfer an amount of finely powdered Tablets (from NLT 20 Tablets) equivalent to 5 mg of diethylcarbamazine citrate to a 50-mL volumetric flask, and dissolve in and dilute with *Solution B* to volume.

Chromatographic system

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Flow rate: 0.8 mL/min

Injection volume: 20 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 diethylcarbamazine citrate ($C_{10}H_{21}N_3O \cdot C_6H_8O_7$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **DISINTEGRATION ⟨701⟩** (for Tablets labeled solely for veterinary use)**:** 30 min

• **DISSOLUTION ⟨711⟩**

Procedure for a pooled sample

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Buffer: 62.48 g/L of monobasic potassium phosphate in water

Sample solutions: Prepare by quantitatively diluting filtered portions of the solution under test with *Buffer* (1:1)

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Analysis: Determine the amount of diethylcarbamazine citrate ($C_{10}H_{21}N_3O \cdot C_6H_8O_7$) dissolved as directed in the *Assay*.

Tolerances: NLT 75% (*Q*) of the labeled amount of diethylcarbamazine citrate ($C_{10}H_{21}N_3O \cdot C_6H_8O_7$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, and **Chromatographic system:** Proceed as directed in the *Assay*.

Citric acid solution: 2 mg/mL of citric acid in *Solution B*

Standard solution: 0.003 mg/mL of USP Diethylcarbamazine Citrate RS in *Solution B*

Sample solution: Transfer an amount of finely powdered Tablets (from NLT 20 Tablets) nominally equivalent to 300 mg of diethylcarbamazine citrate to a 100-mL volumetric flask. Dilute with *Solution B* to volume. Filter or centrifuge, and use the clear filtrate or supernatant.

Analysis

Samples: *Citric acid solution*, *Standard solution*, and *Sample solution*

Calculate the percentage of any individual impurity in the portion of Tablets taken:

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

r_U = peak response of any individual impurity from the *Sample solution*. [Note—Disregard any peak having a retention time corresponding to that of the main peak of the *Citric acid solution*.]

r_S = peak response of diethylcarbamazine citrate from the *Standard solution*

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

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

Acceptance criteria: NMT 0.1%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Diethylcarbamazine Citrate RS

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

Topic/Question	Contact	Expert Committee
DIETHYLCARBAMAZINE CITRATE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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