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Molindone Hydrochloride Tablets

DEFINITION

Molindone Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of molindone hydrochloride ($C_{16}H_{24}N_2O_2 \cdot HCl$).

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard solution: 2.5 mg/mL of USP Molindone Hydrochloride RS in methanol

Sample solution: Nominally 2.5 mg/mL of molindone hydrochloride from finely powdered Tablets in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Alcohol and 1 N hydrochloric acid (95:5)

Spray reagent: Dragendorff's reagent, prepared as directed for technique 3 in *Ordinary Impurities ⟨466⟩, Key for Visualization Techniques*

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Allow the spots to dry, protect the chromatogram from light, and develop in the *Developing solvent system*. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by spraying with *Spray reagent*.

Acceptance criteria: The R_F value of the principal spot from the *Sample solution* corresponds to that from the *Standard solution*.

ASSAY

• **Procedure**

Mobile phase: Dissolve 1.1 g of sodium octanesulfonate in 480 mL of water. Add 520 mL of methanol, 2 mL of glacial acetic acid, and 0.4 mL of triethylamine. Pass through a filter of 0.45-µm pore size and degas.

Diluent: Methanol and 0.01 N hydrochloric acid (40:60)

Internal standard solution: 2 mg/mL of butylparaben prepared as follows. Transfer a suitable amount of butylparaben to a suitable volumetric flask, dissolve in methanol equivalent to 40% of the flask volume, and dilute with water to volume.

Standard solution: 0.5 mg/mL of USP Molindone Hydrochloride RS prepared as follows. Transfer a suitable amount of USP Molindone Hydrochloride RS to a suitable volumetric flask, add *Internal standard solution* equivalent to 10% of the flask volume, and dilute with *Diluent* to volume.

Sample solution: Nominally 0.5 mg/mL of molindone hydrochloride from Tablets prepared as follows. Grind Tablets (NLT 20) to a homogeneous mixture, and transfer a portion equivalent to 50 mg of molindone hydrochloride to a 250-mL conical flask. Add 10.0 mL of *Internal standard solution* and 90.0 mL of *Diluent*, shake for 30 min, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L11

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for molindone and butylparaben are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2 between molindone and butylparaben

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of molindone hydrochloride ($C_{16}H_{24}N_2O_2 \cdot HCl$) in the portion of Tablets taken:

Result = $(R_U/R_S) \times (C_S/C_U) \times 100$

R_U = peak response ratio of molindone to butylparaben from the *Sample solution*

R_S = peak response ratio of molindone to butylparaben from the *Standard solution*

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

C_U = nominal concentration of molindone hydrochloride 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 1: 100 rpm

Time: 30 min

Solution A: Methanol and 0.1 N hydrochloric acid (30:70)

Solution B: Methanol and 0.1 N hydrochloric acid (75:25)

Mobile phase: Dissolve 1.08 g of sodium 1-octanesulfonate in 480 mL of water. Add 520 mL of methanol, 2.0 mL of acetic acid, and 0.4 mL of triethylamine.

Standard solution: 2.4 µg/mL of USP Molindone Hydrochloride RS in *Solution A*

Sample solution: Withdraw a portion of the solution under test, and filter, discarding the first 3 mL of filtrate. Pipet 15.0 mL of this solution into a 25-mL volumetric flask and dilute with *Solution B* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L11

Flow rate: 1.5 mL/min

Injection volume: 100 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Record the chromatograms, and measure the peak heights.

Calculate the percentage of the labeled amount of molindone hydrochloride ($C_{16}H_{24}N_2O_2 \cdot HCl$) dissolved.

Tolerances: NLT 80% (*Q*) of the labeled amount of molindone hydrochloride ($C_{16}H_{24}N_2O_2 \cdot HCl$) is dissolved.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Molindone Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
MOLINDONE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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