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Dronabinol Capsules

DEFINITION

Dronabinol Capsules contain dronabinol in Sesame Oil. Dronabinol Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of dronabinol ($C_{21}H_{30}O_2$).

IDENTIFICATION

The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Methanol, tetrahydrofuran, and water (71:5:24)

System suitability stock solution: 1.0 mg/mL of Δ^8-tetrahydrocannabinol in methanol

System suitability solution: 0.5 mg/mL of USP Δ^9-Tetrahydrocannabinol RS and 0.5 mg/mL of Δ^8-tetrahydrocannabinol. Mix equal volumes of USP Δ^9-Tetrahydrocannabinol RS and *System suitability stock solution*.

Standard solution: 0.2 mg/mL of USP Δ^9-Tetrahydrocannabinol RS in dehydrated alcohol

Sample solution: Equivalent to 0.2 mg/mL of dronabinol, from Capsule contents (NLT 20) in dehydrated alcohol

Chromatographic system

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

Mode: LC

Detector: UV 228 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Guard column: 4.6-mm × 30-mm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution* [Note—The relative retention times for Δ^9-tetrahydrocannabinol and Δ^8-tetrahydrocannabinol are about 1.0 and 1.14, respectively.]

Suitability requirements

Resolution: NLT 2.0 between dronabinol and Δ^8-tetrahydrocannabinol, *System suitability solution*

Tailing factor: NMT 2.0 of Δ^9-tetrahydrocannabinol, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{21}H_{30}O_2$ in the portion of Capsules taken:

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

r_U = peak response of dronabinol from the *Sample solution*

r_S = peak response of dronabinol from the *Standard solution*

C_S = concentration of USP Δ^9-Tetrahydrocannabinol RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 500 mL

Apparatus 2: 50 rpm

Time: 15 min

Analysis: Place 1 Capsule in each vessel, and allow the Capsule to sink to the bottom of the vessel before starting rotation of the blade. Observe the Capsules, and record the time taken for each Capsule shell to rupture.

Tolerances: The requirements are met if all of the Capsules tested rupture in NMT 15 min. If 1 or 2 of the Capsules rupture in NLT 15 but NMT 30 min, repeat the test on 12 additional Capsules. NMT 2 of the total of 18 Capsules tested rupture in NLT 15 min but NMT 30 min.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers, in a cool place.

• **USP Reference Standards** ⟨11⟩

USP Delta-9-Tetrahydrocannabinol RS

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

Topic/Question	Contact	Expert Committee
DRONABINOL CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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