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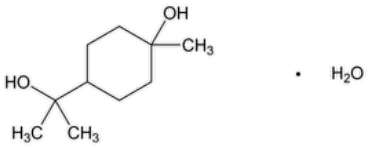
Terpin Hydrate



$C_{10}H_{20}O_2 \cdot H_2O$ 190.28
$C_{10}H_{20}O_2$ 172.27
Cyclohexanemethanol, 4-hydroxy-α,α,4-trimethyl-, monohydrate;
p-Menthane-1,8-diol monohydrate CAS RN®: 2451-01-6.
Anhydrous CAS RN®: 80-53-5.

DEFINITION
Terpin Hydrate contains NLT 98.0% and NMT 100.5% of terpin ($C_{10}H_{20}O_2$), calculated on the anhydrous basis.

IDENTIFICATION
Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Sample: Dried over a suitable desiccant for 4 h
Acceptance criteria: Meets the requirements

• **B.**
Analysis: Add a few drops of sulfuric acid to a hot solution.
Acceptance criteria: The liquid becomes turbid and develops a strong aromatic odor.

ASSAY
• **Procedure**
Internal standard solution: 20 mg/mL of biphenyl in chloroform
Standard solution: Transfer 170 mg of USP Terpin Hydrate RS to a 100-mL volumetric flask, dissolve in 5 mL of alcohol, add 5.00 mL of *Internal standard solution*, and dilute with chloroform to volume.
Sample solution: Transfer 170 mg of Terpin Hydrate to a 100-mL volumetric flask, dissolve in 5 mL of alcohol, add 5.00 mL of *Internal standard solution*, and dilute with chloroform to volume.
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
Mode: GC
Detector: Flame ionization
Column: 3.5-mm × 1.2-m glass; packed with 6% G1 on support S1A
Temperatures
Injection port: 260°
Detector: 260°
Column: 120°
Carrier gas: Nitrogen
Flow rate: Necessary to yield approximate retention times of 7 min for terpin and 11 min for biphenyl
Injection volume: 1 µL
System suitability
Sample: *Standard solution*
Suitability requirements

Resolution: NLT 2.0 between the terpin and biphenyl peaks

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of terpin ($C_{10}H_{20}O_2$) in the portion of Terpin Hydrate taken:

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

R_U = peak response ratio of terpin to biphenyl from the *Sample solution*

R_S = peak response ratio of terpin to biphenyl from the *Standard solution*

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

C_U = concentration of Terpin Hydrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–100.5% on the anhydrous basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** 9.0%–10.0%

• **Residual Turpentine:** No odor of turpentine oil

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Terpin Hydrate RS

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

Topic/Question	Contact	Expert Committee
TERPIN HYDRATE	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:
Pharmacopeial Forum: Volume No. Information currently unavailable

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