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Terpin Hydrate Oral Solution

DEFINITION

Terpin Hydrate Oral Solution contains, in each 100 mL, NLT 1.53 g and NMT 1.87 g of terpin hydrate ($C_{10}H_{20}O_2 \cdot H_2O$).

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 5.0 mL of *Internal standard solution*, and dilute with chloroform to volume.

Sample solution: Pipet 10 mL of Oral Solution into a separator. Add 20 mL of water and 10 mL of 5 N sodium hydroxide, and extract with three 25-mL portions of chloroform, filtering each, successively, through cotton. Rinse the cotton with chloroform. To the combined rinse and extracts add 5.0 mL of *Internal standard solution*.

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 amount of terpin hydrate ($C_{10}H_{20}O_2 \cdot H_2O$) in 100 mL of Oral Solution taken:

$$\text{Result} = (R_U/R_S) \times W_S \times V$$

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*

W_S = weight of [USP Terpin Hydrate RS](#), calculated on the anhydrous basis (g)

V = volume of sample, 10 mL

Acceptance criteria: 1.53–1.87 g

SPECIFIC TESTS

• [ALCOHOL DETERMINATION, Method II \(611\)](#): 90.0%–110.0% of the labeled amount of C_2H_5OH

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 ORAL SOLUTION	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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