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Camphorated Phenol Topical Solution

DEFINITION

Camphorated Phenol Topical Solution is a solution of Camphor and Phenol in eucalyptus oil and Light Mineral Oil. It contains NLT 90.0% and NMT 110.0% of the labeled amount of camphor ($C_{10}H_{10}$ 0) and phenol ($C_{6}H_{6}$ 0).

IDENTIFICATION

• A. The retention times of the camphor and phenol peaks of the Sample solution correspond to those of the Standard solution, as obtained in the Assay.

ASSAY

• PROCEDURE

Internal standard solution: 10 mg/mL of n-dodecane in chloroform

Standard stock solution: 9.6 mg/mL of USP Phenol RS and 22.4 mg/mL of USP Camphor RS, in chloroform

Standard solution: 0.96 mg/mL of <u>USP Phenol RS</u>, 2.24 mg/mL of of <u>USP Camphor RS</u>, and 1 mg/mL of *n*-dodecane in chloroform from the

Standard stock solution and Internal standard solution

Sample solution: Transfer 1 g of Topical Solution to a 50-mL volumetric flask. Add 5.0 mL of *Internal standard solution*, and dilute with chloroform to volume.

Chromatographic system

(See <u>Chromatography (621), System Suitability</u>.)

Mode: GC

Detector: Flame ionization

Column: 2-mm × 1.8-m glass; packed with 100- to 120-mesh S1A, coated with 15% G44

Carrier gas: Helium Temperatures Detector: 200° Column: 140°

Injection volume: 1-2 µL

System suitability

Sample: Standard solution

[Note—The relative retention times are 0.3 for phenol, 0.8 for camphor, and 1.0 for the internal standard.]

Suitability requirements

Resolution: NLT 2.0 between camphor and the internal standard, and NLT 5.0 between phenol and camphor

Relative standard deviation: NMT 2.0% of the peak response ratio of camphor and phenol to the internal standard for five consecutive

injections

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of the labeled amount of camphor (w/w) and phenol (w/w) in the portion of Topical Solution taken:

Result =
$$(R_{II}/R_{\odot}) \times (C_{\odot}/C_{II}) \times 100$$

R_{II} = peak response ratio of the corresponding analyte to the internal standard from the Sample solution

R_c = peak response ratio of the corresponding analyte to the internal standard from the *Standard solution*

 $C_{
m c}$ = concentration of the appropriate USP Reference Standard in the Standard solution (mg/mL)

C₁₁ = nominal concentration of the appropriate analyte in the Sample solution (mg/mL)

Acceptance criteria: 90.0%-110.0%

SPECIFIC TESTS

• SPECIFIC GRAVITY (841): 0.840-0.865

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE: Preserve in tight containers. Store at room temperature, avoid excessive heat, and close the cover after each use.
- USP REFERENCE STANDARDS (11)

USP Camphor RS
USP Phenol RS

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

Topic/Question	Contact	Expert Committee
CAMPHORATED PHENOL TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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