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Camphorated Phenol Topical Gel

DEFINITION

Camphorated Phenol Topical Gel is a mixture of Camphor and Phenol in a suitable gel vehicle. It contains NLT 90.0% and NMT 110.0% of the labeled amount of camphor ($C_{10}H_{16}O$) and phenol (C_6H_6O).

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 [USP Phenol RS](#), 2.24 mg/mL of [USP Camphor RS](#), and 1 mg/mL of *n*-dodecane in chloroform from *Standard stock solution* and *Internal standard solution*

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

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

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 Gel taken:

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

R_U = peak response ratio of the corresponding analyte to the internal standard from the *Sample solution*

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

C_S = concentration of the appropriate USP Reference Standard in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

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 GEL	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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