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Menthol Lozenges

DEFINITION
Menthol Lozenges contain NLT 90.0% and NMT 125.0% of the labeled amount of menthol ($C_{10}H_{20}O$), in a suitable molded base.

IDENTIFICATION
• **A.** The retention time of the menthol peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Solution A: 250 mg/mL of sodium chloride in water

Internal standard solution: 2 mg/mL of anethole in hexanes

Standard solution: 0.20*L* mg/mL of USP Menthol RS in *Internal standard solution*, where *L* is the labeled quantity, in mg, of menthol in each Lozenge

Sample solution: Transfer 20 Lozenges to a 1-L screw-capped conical flask. [Note—Use caps with inert white rubber liners.] Add 200 mL of water, 260 mL of *Solution A*, and 100.0 mL of the *Internal standard solution*, and shake by mechanical means for 30 min. Allow the phases to separate, and transfer a portion of the hexanes phase to a suitable container.

Chromatographic system
(See *Chromatography (621), System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m fused silica; coated with a 1-µm layer of G16 stationary phase

Temperatures

Column: 125° (isothermally)

Injection port: 250°

Detector: 250°

Carrier gas: Helium

Flow rate: 10 mL/min

Injection volume: 1 µL

Injection type: Split ratio of 10:1

System suitability

Sample: *Standard solution*

[Note—The relative retention times for menthol and anethole are about 0.5 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 15 between menthol and anethole

Tailing factor: NMT 2.0 for menthol and anethole

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of menthol ($C_{10}H_{20}O$) in the portion of Lozenges taken:

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

R_U = peak response ratio of the menthol to the anethole from the *Sample solution*

R_S = peak response ratio of the menthol to the anethole from the *Standard solution*

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

C_U = nominal concentration of menthol in the hexanes phase of the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–125.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩
  USP Menthol RS

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

Topic/Question	Contact	Expert Committee
MENTHOL LOZENGES	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

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