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Hexylresorcinol Lozenges

DEFINITION
Hexylresorcinol Lozenges contain NLT 90.0% and NMT 110.0% of the labeled amount of hexylresorcinol ($C_{12}H_{18}O_2$).

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

ASSAY
• **Procedure**

Buffer: Dissolve 3.4 g of monobasic potassium phosphate in 850 mL of water. Adjust with phosphoric acid to a pH of 3.0 ± 0.05, dilute with water to 1000 mL, mix, and pass through a suitable filter of 0.5-µm or finer pore size.

Mobile phase: Methanol and *Buffer* (65:35)

Internal standard solution: 0.25 mg/mL of hexanophenone in *Mobile phase*

Standard stock solution: 0.4 mg/mL of USP Hexylresorcinol RS in *Mobile phase*

Standard solution: Transfer 10.0 mL of *Standard stock solution* and 10.0 mL of *Internal standard solution* to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume. This solution contains 0.08 mg/mL of USP Hexylresorcinol RS.

Sample solution: Nominally 0.08 mg/mL of hexylresorcinol prepared as follows. Transfer the equivalent to 4 mg of hexylresorcinol from Lozenges (NLT 20 Lozenges, weighed and pulverized) to a 50-mL volumetric flask. Add 10.0 mL of *Internal standard solution* and 20 mL of *Mobile phase*, and shake until dissolved. Dilute with *Mobile phase* to 50 mL, and mix. Pass a portion of this solution through a suitable filter of 0.5-µm or finer pore size, and use the filtrate.

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 15-cm; packing L7

Column temperature: 37 ± 2°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution* and *Sample solution*

[Note—The relative retention times for hexylresorcinol and hexanophenone are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.2 between the hexylresorcinol peak and the nearest adjacent peak, *Sample solution*

Column efficiency: NLT 1500 theoretical plates, *Standard solution*

Tailing factor: 0.9–1.4, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hexylresorcinol ($C_{12}H_{18}O_2$) 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 hexylresorcinol to hexanophenone in the *Sample solution*

R_S = peak response ratio of hexylresorcinol to hexanophenone in the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**
USP Hexylresorcinol RS

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

Topic/Question	Contact	Expert Committee
HEXYLRESORCINOL LOZENGES	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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