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Nitroglycerin Ointment

DEFINITION

Nitroglycerin Ointment is Diluted Nitroglycerin in a suitable ointment base. It contains NLT 90.0% and NMT 115.0% of the labeled amount of nitroglycerin ($C_3H_5N_3O_9$).

IDENTIFICATION

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

ASSAY

• **Procedure**

Mobile phase: Methanol and water (500:500)

Standard solution: 0.075 mg/mL of nitroglycerin from USP Diluted Nitroglycerin RS in *Mobile phase*

Sample solution: Transfer a quantity of Ointment equivalent to 2.0 mg of nitroglycerin to a glass-stoppered, 50-mL conical flask, and add 25.0 mL of *Mobile phase*. Immerse the flask containing the sample in a water bath maintained at a temperature of 50° for 10 min. Shake intermittently until the sample is dispersed. Remove the flask from the bath, and shake vigorously for 1 min to obtain a coagulated solid. Repeat the heating and shaking steps one more time, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L1

[Note—If necessary, a short precolumn that contains packing L1 may be used.]

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3000 theoretical plates

Tailing factor: NMT 2.5

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of of the labeled amount of nitroglycerin ($C_3H_5N_3O_9$) in the portion of Ointment taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of nitroglycerin in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

• **Homogeneity**

Analysis: In the case of single-dose containers, perform the *Assay* on specimens from each of 10 containers. In the case of multiple-dose containers, perform the *Assay* on one sample from the top and one from the bottom of each of five containers.

Acceptance criteria: Each sample contains NLT 90.0% and NMT 110.0% of the mean value.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Label multiple-dose containers with a direction to close tightly immediately after each use.

• **USP Reference Standards** ⟨11⟩

USP Diluted Nitroglycerin RS

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

Topic/Question	Contact	Expert Committee
NITROGLYCERIN OINTMENT	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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