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Nitroglycerin Injection

DEFINITION

Nitroglycerin Injection is a sterile solution prepared from Diluted Nitroglycerin; the solvent may contain Alcohol, Propylene Glycol, and Water for Injection. Nitroglycerin Injection contains NLT 90.0% and NMT 110.0% 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 measured volume of Injection equivalent to 7.5 mg of nitroglycerin to a 100-mL volumetric flask, and dissolve in and dilute with *Mobile phase* to volume.

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 the labeled amount of nitroglycerin ($C_3H_5N_3O_9$) in the portion of Injection 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 the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

- [ALCOHOL DETERMINATION, Method II\(611\)](#)

Sample: Use isopropyl alcohol as the internal standard.

Acceptance criteria: 90.0%–110.0% of the labeled amount of C_2H_5OH

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST** (85): NMT 0.1 USP Endotoxin Unit/µg of nitroglycerin
- **pH** (791)
Sample: To 5 mL of the Injection add 5 mL of water and 1 drop of saturated potassium chloride solution.
Acceptance criteria: 3.0–6.5
- **PARTICULATE MATTER IN INJECTIONS** (788): Meets the requirements for small-volume injections
- **OTHER REQUIREMENTS:** It meets the requirements in *Injections and Implanted Drug Products* (1).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type II glass.
- **LABELING:** Where necessary, label it to indicate that it is to be diluted before 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 INJECTION	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](#)

Most Recently Appeared In:

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