

Status: Currently Official on 16-Feb-2025  
Official Date: Official as of 01-May-2018  
Document Type: USP Monographs  
DocId: GUID-7E9D2D53-D034-44D7-A8FE-609C1D125B82\_3\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M56968\\_03\\_01](https://doi.org/10.31003/USPNF_M56968_03_01)  
DOI Ref: shk96

© 2025 USPC  
Do not distribute

## 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  $\times$  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  $\mu$ L

#### 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	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM22020 Small Molecules 2

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. PF 44(3)

**Current DocID: GUID-7E9D2D53-D034-44D7-A8FE-609C1D125B82\_3\_en-US**

**Previous DocID: GUID-7E9D2D53-D034-44D7-A8FE-609C1D125B82\_1\_en-US**

**DOI:** [https://doi.org/10.31003/USPNF\\_M56968\\_03\\_01](https://doi.org/10.31003/USPNF_M56968_03_01)

**DOI ref:** [shk96](#)