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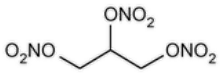
# Diluted Nitroglycerin



$C_3H_5N_3O_9$ 227.09

1,2,3-Propanetriol, trinitrate;

Nitroglycerin CAS RN®: 55-63-0; UNII: G59M7S0WS3.

## DEFINITION

Diluted Nitroglycerin is a mixture of nitroglycerin ($C_3H_5N_3O_9$) with lactose, dextrose, alcohol, propylene glycol, or other suitable inert excipient to permit safe handling. It contains NLT 90.0% and NMT 110.0% of the labeled amount of $C_3H_5N_3O_9$. It usually contains NMT 10% of nitroglycerin ($C_3H_5N_3O_9$). [**Caution—**Taking into consideration the concentration and amount of nitroglycerin ($C_3H_5N_3O_9$) in Diluted Nitroglycerin, exercise appropriate precautions when handling this material. Nitroglycerin is a powerful explosive and can be detonated by percussion or excessive heat. Do not isolate nitroglycerin ($C_3H_5N_3O_9$).]

## IDENTIFICATION

• **A.** The $R_F$ value of the principal spot of *Sample solution A* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Organic Impurities*.

• **B.** 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 (1:1)

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

**Sample solution:** Transfer a portion of Diluted Nitroglycerin, equivalent to 7.5 mg of nitroglycerin, to a 100-mL volumetric flask, and dissolve in 75 mL of *Mobile phase*. If necessary, sonicate for 2 min or until the solid is totally dispersed, then shake by mechanical means for 30 min. Dilute with *Mobile phase* to volume, 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 size:** 20 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Column efficiency:** NLT 3000 theoretical plates

**Tailing factor:** NMT 2.5 for the analyte peak

**Relative standard deviation:** NMT 3.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of $C_3H_5N_3O_9$ in the portion of Diluted Nitroglycerin 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%

## IMPURITIES

### Organic Impurities

- **Procedure**

**Standard solution:** 400 µg/mL of nitroglycerin from USP Diluted Nitroglycerin RS in methanol

**Sample solution A:** Prepare a clear solution containing 400 µg/mL of nitroglycerin from Diluted Nitroglycerin in methanol.

**Sample solution B:** 20 mg/mL of nitroglycerin in methanol from Diluted Nitroglycerin. Centrifuge a portion, if necessary, to obtain a clear liquid phase.

**Chromatographic system**

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

**Adsorbent:** 0.25-mm layer of chromatographic silica gel mixture

**Application volume:** 20 µL each of *Sample solution A* and *Sample solution B*; 5, 10, 15, and 20 µL of the *Standard solution*

**Developing solvent system:** Toluene and ethyl acetate (4:1)

**Spray reagent:** Diphenylamine in methanol (1 in 100)

**Analysis**

**Samples:** *Standard solution*, *Sample solution A*, and *Sample solution B*

Apply the *Samples* to a suitable thin-layer chromatographic plate. Develop the chromatograms in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Spray the plate with *Spray reagent*, and irradiate the plate with short- and long-wavelength UV light for 15 min.

**Acceptance criteria:** Any spot from *Sample solution B,* other than the principal spot, is not more intense than the spot from the 20-µL application of the *Standard solution*. Compare the intensities of any secondary spots observed from *Sample solution B* with those of the principal spots from the *Standard solution* (corresponding to 0.5%, 1.0%, 1.5%, and 2.0%, respectively): the sum of the intensities of the secondary spots from *Sample solution B* is NMT 3%. [Note—Nitrates of glycerin typically have $R_F$ values of 0.21, 0.37, and 0.61 for mono-, di-, and tri-substituted glycerins, respectively.]

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and prevent exposure to excessive heat. Store at 25°, excursions permitted between 15° and 30°.
- **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 |
|---|---|---|
| DILUTED NITROGLYCERIN | Documentary Standards Support | SM22020 Small Molecules 2 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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