https://trungtamthuoc.com/

Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-EAACF52C-B739-4339-AF0D-38DBAC2E9152_1_en-US
DOI: https://doi.org/10.31003/USPNF_M56980_01_01
DOI Ref: p0llk

© 2025 USPC
Do not distribute

Nitroglycerin Sublingual Tablets

DEFINITION
Nitroglycerin Sublingual Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of nitroglycerin ($C_3H_5N_3O_9$).

IDENTIFICATION

- **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

  Standard solution: Equivalent to 1 mg/mL of nitroglycerin in acetone from USP Diluted Nitroglycerin RS

  Sample solution: Equivalent to 1 mg/mL of nitroglycerin from powdered Sublingual Tablets, in acetone. Shake by mechanical means for 30 min, and filter.

  Developing solvent system: Toluene, ethyl acetate, and glacial acetic acid (16:4:1)

  Analysis: Proceed as directed. Spray with a solution (1 in 100) of diphenylamine in methanol, and irradiate the plate with short- and long-wavelength UV light for 10 min.

  Acceptance criteria: Meets the requirements

- **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 (50:50)

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

  Sample solution: Nominally equivalent to 0.075 mg/mL of nitroglycerin from powdered Sublingual Tablets (NLT 20 Sublingual Tablets) in *Mobile phase*

  Chromatographic system

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

  Mode: LC

  Detector: UV 220 nm

  Column: 4.6-mm × 25-cm; packing L1. [Note—If necessary, use a short precolumn that contains packing L1.]

  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 Sublingual Tablets 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)

OFFICIAL

www.webofpharma.com

https://trungtamthuoc.com/

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **Disintegration** ⟨701⟩

Determined as set forth for Sublingual Tablets

Time: 2 min

Acceptance criteria: Meets the requirements

• **Uniformity of Dosage Units** ⟨905⟩

Procedure for content uniformity

Mobile phase, Standard solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample solution: 0.075 mg/mL of nitroglycerin in *Mobile phase*, from 1 Sublingual Tablet

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of nitroglycerin ($C_3H_5N_3O_9$) in the Sublingual Tablet 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: The content of each of the 10 Sublingual Tablets is within the range of 75.0%–135.0% of the labeled claim. If the content of NMT 1 Sublingual Tablet is outside the range of 75.0%–135.0% and if the content of none of the Sublingual Tablets is outside the range of 60.0%–150.0%, test 20 additional units. The requirements are met if the content of each of the additional 20 units falls within the range of 75.0%–135.0% of the labeled claim.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, preferably of glass, and store at controlled room temperature. Each container holds NMT 100 Sublingual Tablets.

• **Labeling:** The labeling indicates that the Sublingual Tablets are for sublingual use, and the label directs that the Sublingual Tablets be dispensed in the original, unopened container, labeled with the following statement directed to the patient. “Warning: To prevent loss of potency, keep these tablets in the original container or in a supplemental nitroglycerin container specifically labeled as being suitable for Nitroglycerin Sublingual Tablets. 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 SUBLINGUAL TABLETS	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:
Pharmacopeial Forum: Volume No. PF 44(3)

Current DocID: GUID-EAACF52C-B739-4339-AF0D-38DBAC2E9152_1_en-US

DOI: https://doi.org/10.31003/USPNF_M56980_01_01

DOI ref: p0llk

OFFICIAL

www.webofpharma.com