

Glyceryl trinitrate tablets (Glycerylis trinitratis compressi)

Other name. Nitroglycerin tablets.

Category. Antianginal drug.

Storage. Glyceryl trinitrate tablets should be kept in a tightly closed container, preferably made of glass, with a screw closure lined with aluminium or tin foil, protected from light, and stored at a temperature not exceeding 20 °C. To prevent loss of potency, the tablets should be kept in the original container. Each container should hold not more than 100 tablets. After each use the container should be closed immediately.

Labelling. The designation on the container should state that the tablets are for sublingual use. Expiry date.

Additional information. Strength in the current WHO Model list of essential medicines: 500 µg.

CAUTION: *Undiluted glyceryl trinitrate can explode by percussion or excessive heat. Avoid keeping isolated small amounts.*

Requirements

Comply with the monograph for "[Tablets](#)".

Definition. Glyceryl trinitrate tablets are tablets for sublingual use.

Glyceryl trinitrate tablets contain not less than **80.0%** and not more than **120.0%** of the amount of $C_3H_5N_3O_9$ stated on the label.

Identity tests

A. Shake a quantity of the powdered tablets equivalent to 0.50 mg of Glyceryl trinitrate with 5 mL of dehydrated ethanol R, filter, and evaporate the filtrate to dryness using a stream of air. To the residue add 3–4 drops of sodium hydroxide (~80 g/l) TS and 3 mL of ferrous sulfate (15 g/l) TS and shake; a greenish brown precipitate is produced.

B. Extract a quantity of the powdered tablets equivalent to 5 mg of Glyceryl trinitrate with 3 mL of ethanol (~750 g/l) TS and filter. To the filtrate add carefully 1 mL of diphenylamine/sulfuric acid TS in a manner to form a lower layer; a dark blue colour is produced at the interface of the two layers.

Test for the absence of decomposition. Shake a quantity of the powdered tablets equivalent to 0.50 mg of Glyceryl trinitrate with 5 mL of water and filter. To the filtrate add 0.1 g of potassium iodide R, 2 drops of sulfuric acid (~100 g/l) TS, and 1 mL of starch TS; the liquid remains colourless. Add 1 mL of sodium hydroxide (~80 g/l) TS and heat gently to boiling. Cool and add 3 mL of sulfuric acid (~100 g/l) TS; a dark blue colour is immediately produced.

Assay. Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 1 mg of Glyceryl trinitrate, accurately weighed, add 4.5 mL of glacial acetic acid R and 0.5 mL of water, shake for 1 hour, and centrifuge. For the *reference solution*, dissolve 133.5 mg of potassium nitrate R, previously dried at 105 °C, in sufficient water to produce 50 mL. Transfer 10 mL to a volumetric flask and add sufficient glacial acetic acid R to produce 100 mL. To 1 mL of each of the clear *sample* and *reference solutions* add 2 mL of phenoldisulfonic acid TS, mix, and allow to stand for 15 minutes. Then add 8 mL of water, mix well, allow to cool, and add slowly with swirling 10 mL of ammonia (~260 g/l) TS. Cool and dilute to 20 mL with water.

Measure the absorbances of both solutions at the maximum at about 405 nm against a solvent cell containing a reagent blank. Calculate the amount in mg of $C_3H_5N_3O_9$ in the sample being examined by comparison with the *reference solution*. Each mL of the potassium nitrate *reference solution* is equivalent to 0.2000 mg of $C_3H_5N_3O_9$.

Disintegration test. Complies with the test for [5.3 Disintegration test for tablets and capsules](#). Time period: 2 minutes.

Uniformity of content. For the *sample solution*, place 10 powdered tablets in 10 separate centrifuge tubes containing a few glass beads, add 4.5 mL of glacial acetic acid R and 0.5 mL of water, shake for 1 hour, and centrifuge.

For the *reference solution*, dissolve 133.5 mg of potassium nitrate R, previously dried at 105 °C, in sufficient water to produce 50 mL. Transfer 10 mL to a volumetric flask and add sufficient glacial acetic acid R to produce 100 mL.

For tablets containing *0.4 to 0.6 mg of Glyceryl trinitrate*, use 1 mL of the clear *sample solution* and 1 mL of a mixture of equal volumes of the *reference solution* and glacial acetic acid R. To both solutions add 2 mL of phenoldisulfonic acid TS, mix, and allow to stand for 15 minutes. Then add 8 mL of water, mix well, allow to cool, and add slowly with swirling 10 mL of ammonia (~260 g/l) TS. Cool and dilute to 20 mL with water.

For tablets containing *0.2 to 0.3 mg of Glyceryl trinitrate*, use 2 mL of the clear *sample solution* and 2 mL of a mixture of 3 volumes of glacial acetic acid R and 1 volume of the *reference solution*. To both solutions add 2 mL of phenoldisulfonic acid TS, mix, and allow to stand for 15 minutes. Then add 8 mL of water, mix well, allow to cool, and add slowly with swirling 10 mL of ammonia (~260 g/l) TS. Cool and dilute to 20 mL with water.

For tablets containing *less than 0.2 mg of Glyceryl trinitrate*, use 2 mL of the clear *sample solution* and 2 mL of a mixture of 7 volumes of glacial acetic acid R and 1 volume of the *reference solution*. To both solutions add 2 mL of phenoldisulfonic acid TS, mix, and allow to stand for 15 minutes. Then add 8 mL of water, mix well, allow to cool, and add slowly with swirling 10 mL of ammonia (~260 g/l) TS. Cool and dilute to 20 mL with water.

Measure the absorbances in the *sample* and *reference solutions* of all three concentrations at the maximum at about 405 nm against a solvent cell containing a reagent blank. Calculate the amount in mg of $C_3H_5N_3O_9$ in the sample being examined by comparison with the *reference solution*. Each mL of the potassium nitrate *reference solution* is equivalent to 0.2000 mg of $C_3H_5N_3O_9$.

The tablets comply with the test for [5.1 Uniformity of content for single-dose preparations](#).