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Glycerin Suppositories

» Glycerin Suppositories contain Glycerin solidified with Sodium Stearate. [NOTE—If preferred, the Sodium Stearate for Glycerin Suppositories may be prepared during the making of the Suppositories by the direct reaction between Stearic Acid and Sodium Bicarbonate, Sodium Carbonate, or Sodium Hydroxide, these being taken in the correct proportion.] Glycerin Suppositories contain not less than 75.0 percent and not more than 90.0 percent, by weight, of glycerin ($C_3H_8O_3$).

Packaging and storage—Preserve in well-closed containers.

USP REFERENCE STANDARDS ⟨11⟩—

USP Stearic Acid RS

Identification—

A: Dissolve 1 g of sodium borate in 100 mL of water, add 25 drops of phenolphthalein TS, and mix. To a test tube containing 0.5 mL of this solution add 2 drops of 1 Suppository that has been melted: the pink solution becomes colorless, and when it is heated the pink color reappears.

B: Disperse 12 Suppositories in about 125 mL of water in a 250-mL beaker on a hot plate. Cool, add 1.5 mL of hydrochloric acid, and pour the mixture into a 250-mL separator. Extract with 75 mL of hexanes, discarding the lower aqueous layer and collecting the organic layer in a beaker. Evaporate with the aid of a steam bath to near dryness: the IR absorption spectrum of a mineral oil dispersion of the residue so obtained exhibits maxima only at the same wavelengths as those of a mineral oil dispersion of USP Stearic Acid RS.

WATER DETERMINATION, *Method I* ⟨921⟩: not more than 15.0%.

Assay—Transfer an accurately weighed quantity of Suppositories, equivalent to about 250 mg of glycerin, to a 250-mL volumetric flask. Dissolve in water, dilute with water to volume, and mix. Pipet 5 mL of this solution into a 250-mL conical flask, and add 50.0 mL of a reagent prepared by mixing 40 mL of dilute sulfuric acid (1 in 20) with 60 mL of potassium periodate solution (1 in 1000) acidified with 3 to 5 drops of sulfuric acid. Heat the solution on a steam bath for 15 minutes, cool to room temperature, and add 1 g of potassium iodide. Allow the flask to stand for 5 minutes, and titrate with 0.02 N sodium thiosulfate VS, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination, using water in place of Suppositories, and note the difference in volumes required. Each mL of the difference in volume of 0.02 N sodium thiosulfate consumed is equivalent to 0.4604 mg of glycerin ($C_3H_8O_3$).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
GLYCERIN SUPPOSITORIES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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