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Theophylline Sodium Glycinate Tablets

» Theophylline Sodium Glycinate Tablets contain an amount of theophylline sodium glycinate equivalent to not less than 93.0 percent and not more than 107.0 percent of the labeled amount of anhydrous theophylline ($C_7H_8N_4O_2$).

Packaging and storage—Preserve in well-closed containers.

Labeling—Label the Tablets to state both the content of theophylline sodium glycinate and the content of anhydrous theophylline.

USP Reference standards ⟨11⟩—
USP Theophylline RS

Identification—Triturate a quantity of finely powdered Tablets, equivalent to about 500 mg of theophylline, with 10-mL and 15-mL portions of solvent hexane, and discard the solvent hexane. Triturate the residue with two 10-mL portions of a mixture of equal volumes of 6 N ammonium hydroxide and water, and filter each time. Evaporate the combined filtrates to about 5 mL, neutralize, if necessary, with 6 N acetic acid, using litmus, and cool to about 15°, with stirring. Collect the precipitate on a filter, wash it with cold water, and dry at 105° for 1 hour: the theophylline so obtained melts between 270° and 274°, the procedure for *Class I* being used (see *Melting Range or Temperature* ⟨741⟩), and responds to *Identification* test *B* under *Theophylline Sodium Glycinate*.

Dissolution ⟨711⟩—
Medium: water; 900 mL.
Apparatus 1: 100 rpm.
Time: 45 minutes.
Procedure—Determine the amount of anhydrous theophylline ($C_7H_8N_4O_2$) dissolved from UV absorbances at the wavelength of maximum absorbance at about 272 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Theophylline RS in the same medium.
Tolerances—Not less than 75% *(Q)* of the labeled amount of anhydrous $C_7H_8N_4O_2$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—Place 20 Tablets in a 200-mL volumetric flask, add 50 mL of water, and when the tablets have disintegrated add 50 mL of 6 N ammonium hydroxide. Shake until no more dissolves, then dilute with water to volume, mix, and filter through a dry filter into a dry flask, discarding the first 20 mL of the filtrate. Transfer an accurately measured aliquot of the subsequent filtrate, equivalent to about 250 mg of theophylline, to a 250-mL conical flask, add 20.0 mL of 0.1 N silver nitrate VS, and heat on a steam bath for 15 minutes. Filter through a filter crucible under reduced pressure, and wash the precipitate with three 10-mL portions of water. Acidify the combined filtrate and washings with nitric acid, and add an excess of 3 mL of the acid. Cool, add 2 mL of ferric ammonium sulfate TS, and titrate the excess silver nitrate with 0.1 N ammonium thiocyanate VS. Each mL of 0.1 N silver nitrate is equivalent to 18.02 mg of $C_7H_8N_4O_2$.

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

Topic/Question	Contact	Expert Committee
THEOPHYLLINE SODIUM GLYCINATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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