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Theophylline Sodium Glycinate Oral Solution

» Theophylline Sodium Glycinate Oral Solution contains 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 (C₇H₈N₄O₂).

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—
[USP Theophylline RS](#)

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

Identification—Mix a volume of Oral Solution, equivalent to about 500 mg of theophylline, with 10 mL of 6 N ammonium hydroxide, and evaporate on a steam bath to a volume of about 20 mL. Neutralize with 6 N acetic acid to litmus, and cool, with stirring, to about 15°. Collect the precipitate on a filter, wash with cold water, and dry at 105° for 4 hours: the theophylline so obtained melts between 270° and 274°, the procedure for *Class I* being used (see [Melting Range or Temperature \(741\)](#)), and meets the requirements for *Identification* test *B* under [Theophylline Sodium Glycinate](#).

pH (791): between 8.3 and 9.1.

ALCOHOL DETERMINATION, Method II (611): between 17.0% and 23.0% of C₂H₅OH.

Assay—

Buffer solution, Mobile phase, Internal standard solution, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under [Theophylline](#).
Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 220 mg of theophylline sodium glycinate, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, add 20.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix.
Procedure—Proceed as directed for *Procedure* in the Assay under [Theophylline](#). Calculate the quantity, in mg, of anhydrous theophylline (C₇H₈N₄O₂) in each mL of the Oral Solution taken by the formula:

$$(1000C/V)(R_U/R_S)$$

in which V is the volume, in mL, of Oral Solution taken, and the other terms are as defined therein.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
THEOPHYLLINE SODIUM GLYCINATE ORAL SOLUTION	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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