Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-F5E356D2-1229-4CDB-9AFA-74EAB4E9C1F1_1_en-US
DOI: https://doi.org/10.31003/USPNF_M82170_01_01
DOI Ref: hz37p

Theophylline Compounded Oral Suspension

DEFINITION

Theophylline Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of theophylline ($C_7H_8N_4O_2$).

Prepare Theophylline Compounded Oral Suspension 5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Theophylline	500 mg
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

Calculate the required quantity of each ingredient for the total amount to be prepared. Calculate the amount of *Theophylline* on the anhydrous basis. If using tablets, place the required number in a suitable mortar, and comminute to a fine powder, or use *Theophylline* powder. Add about 20 mL of the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated container. Add enough of the liquid *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: Dissolve 2.500 g of sodium citrate and 1.633 g of citric acid (anhydrous) in 850 mL of ASTM Type I water, add 150 mL of methanol, and pass through 0.45-µm membrane filters.

Solution B: Acetonitrile

Mobile phase: See *Table 1*. Make adjustments, if necessary.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	100	0.0
20.0	100	0.0
20.01	5.0	95.0
25.0	5.0	95.0
25.01	100	0.0

Diluent: *Solution A*

System suitability solution: 0.10 mg/mL of USP Theophylline RS and 0.20 mg/mL of USP Caffeine RS in *Solution A*

Standard solution: 0.10 mg/mL of USP Theophylline RS in *Solution A*

Sample solution: 0.10 mg/mL of theophylline prepared from Oral Suspension and *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 3.0 between the theophylline and caffeine peaks

Column efficiency: NLT 1000 theoretical plates for the theophylline peak

Tailing factor: NMT 1.5 for the theophylline peak

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of theophylline ($C_7H_8N_4O_2$) in the portion of Oral Suspension 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 USP Theophylline RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of theophylline in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature. Do not refrigerate.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label to state that it is to be well shaken before use, protected from light, not to be refrigerated, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Caffeine RS

USP Theophylline RS

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

Topic/Question	Contact	Expert Committee
THEOPHYLLINE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(1)

Current DocID: GUID-F5E356D2-1229-4CDB-9AFA-74EAB4E9C1F1_1_en-US

DOI: https://doi.org/10.31003/USPNF_M82170_01_01

DOI ref: hz37p