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Pentoxifylline Compounded Oral Suspension

DEFINITION

Pentoxifylline Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of pentoxifylline ($C_{13}H_{18}N_4O_3$).

Prepare Pentoxifylline Compounded Oral Suspension 20 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Pentoxifylline extended-release tablets[a] equivalent to	2 g of pentoxifylline
Purified Water, *USP*, a sufficient quantity to make	100 mL

[a] Trental 400-mg tablets, sanofi-aventis, Somerville, NJ.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Pentoxifylline extended-release tablets* in a suitable mortar, add *Purified Water* in small portions, and triturate to make a smooth paste. Add increasing volumes of *Purified Water* to make a pentoxifylline liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough *Purified Water* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 50 mM monobasic potassium phosphate buffer, adjusted with phosphoric acid to a pH of 3.2

Mobile phase: Acetonitrile and *Solution A* (20:80). Pass through a filter of 0.45-µm pore size, and degas.

Internal standard solution: 100 µg/mL of caffeine in *Mobile phase*

Standard stock solution: 20 mg/mL of USP Pentoxifylline RS in *Mobile phase*

Standard solution: Pipet 1.0 mL of *Standard stock solution* into a 15-mL conical centrifuge tube, and add 9 mL of deionized water. Mix the sample for 30 s in a vortex mixer, and centrifuge for 30 min at 1250 × g. Pipet 50 µL of the supernatant into a separate borosilicate culture tube, dilute with 575 µL of *Mobile phase*, and add 625 µL of *Internal standard solution* to obtain a solution having a nominal concentration of 80 µg/mL of pentoxifylline and 50 µg/mL of caffeine.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.0 mL of Oral Suspension into a 15-mL conical centrifuge tube, and add 9 mL of deionized water. Mix the sample for 30 s in a vortex mixer, and centrifuge for 30 min at 1250 × g. Pipet 50 µL of the supernatant into a separate borosilicate culture tube, dilute with 575 µL of *Mobile phase*, and add 625 µL of *Internal standard solution* to obtain a solution having a nominal concentration of 80 µg/mL of pentoxifylline and 50 µg/mL of caffeine.

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: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for caffeine and pentoxifylline are about 0.42 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 10.0 between pentoxifylline and caffeine

Column efficiency: NLT 10,000 theoretical plates

Tailing factor: NMT 2.0 for the pentoxifylline 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 pentoxifylline ($C_{13}H_{18}N_4O_3$) in the portion of Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of pentoxifylline to the internal standard from the *Sample solution*

R_S = peak response ratio of pentoxifylline to the internal standard from the *Standard solution*

C_S = concentration of USP Pentoxifylline RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of pentoxifylline in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 5.9–7.7

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **Beyond-Use Date:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator or at controlled room temperature
- **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.
- **USP Reference Standards ⟨11⟩**
  USP Pentoxifylline RS

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

Topic/Question	Contact	Expert Committee
PENTOXIFYLLINE 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

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