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Theophylline in Dextrose Injection

DEFINITION
Theophylline in Dextrose Injection is a sterile solution of Theophylline and Dextrose in Water for Injection. It contains NLT 93.0% and NMT 107.0% of the labeled amount of anhydrous theophylline ($C_7H_8N_4O_2$) and NLT 95.0% and NMT 105.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$).

IDENTIFICATION

- A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- C.**

Sample solution: Theophylline in Dextrose Injection

Analysis: Add a few drops of the *Sample solution* to 5 mL of hot [alkaline cupric tartrate TS](#).

Acceptance criteria: A red-to-orange precipitate of cuprous oxide is formed.

ASSAY

- THEOPHYLLINE**

Solution A: 10 mM [ammonium acetate](#) prepared as follows. Transfer 771 mg of [ammonium acetate](#) to a 1-L volumetric flask, and dissolve in 80% of the flask volume of [water](#). Adjust with [glacial acetic acid](#) to a pH of 4.8 and dilute with [water](#) to volume. Pass through a suitable filter of 0.2-µm pore size.

Solution B: Methanol

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	93.5	6.5
2.5	93.5	6.5
5.0	10	90
5.1	93.5	6.5
7.0	93.5	6.5

Standard solution: 0.1 mg/mL of [USP Theophylline RS](#)

Sample solution: Nominally 0.1 mg/mL of theophylline prepared as follows. Transfer 5 mg of theophylline from a volume of Injection to a 50-mL volumetric flask. Dissolve and dilute with [water](#) to volume.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 270 nm. For *Identification A*, use a photodiode array detector in the range of 210–400 nm.

Column: 2.1-mm × 10-cm; 1.7-µm packing [L7](#)

Column temperature: 40°

Flow rate: 0.4 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

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 Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of theophylline from the *Sample solution*

r_S = peak response of theophylline 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: 93.0%–107.0%

• **DEXTROSE**

Sample solution: Nominally 2–5 g of dextrose per 100 mL, prepared as follows. Transfer a volume of Injection containing 2–5 g of dextrose to a 100-mL volumetric flask. Add 0.2 mL of [6 N ammonium hydroxide](#), and dilute with [water](#) to volume.

Analysis

Sample: *Sample solution*

Determine the angular rotation in a suitable polarimeter tube (see [Optical Rotation \(781\)](#)).

Calculate the percentage of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken:

$$\text{Result} = [(100 \times a)/(l \times \alpha)] \times (1/C_U) \times (M_{r1}/M_{r2}) \times 100$$

a = observed angular rotation of the *Sample solution* (°)

l = length of the polarimeter tube (dm)

α = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

C_U = nominal concentration of dextrose in the *Sample solution* (g/100 mL)

M_{r1} = molecular weight of dextrose monohydrate, 198.17

M_{r2} = molecular weight of anhydrous dextrose, 180.16

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **ORGANIC IMPURITIES**

Solution A, Solution B, and Mobile phase: Prepare as directed in the Assay.

System suitability solution: 0.4 µg/mL each of [USP Theophylline Related Compound D RS](#) and 5-hydroxymethylfurfural

Standard solution: 0.4 µg/mL each of [USP Theophylline RS](#) and [USP Theophylline Related Compound D RS](#)

Sample solution: Nominally 400 µg/mL of theophylline in [water](#) prepared as follows. Transfer 4 mg of theophylline from a volume of Injection to a 10-mL volumetric flask. Dissolve and dilute with [water](#) to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 270 nm

Column: 2.1-mm × 10-cm; 1.7-µm packing [L7](#)

Column temperature: 40°

Flow rate: 0.4 mL/min

Injection volume: 2.5 µL