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Aminophylline Rectal Solution

DEFINITION

Aminophylline Rectal Solution is an aqueous solution of Aminophylline, prepared with the aid of Ethylenediamine. It contains an amount of aminophylline equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of anhydrous theophylline ($C_7H_8N_4O_2$).

Rectal Solution may contain an excess of ethylenediamine, but no other substance may be added for the purpose of pH adjustment.

IDENTIFICATION

Change to read:

- A. ▲ **SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: **197K**▲ (CN 1-MAY-2020)

Sample: Dilute an amount of Rectal Solution, equivalent to 500 mg of aminophylline, with water to 20 mL. Add, with constant stirring, 1 mL of 3 N hydrochloric acid or enough to precipitate the theophylline completely, and filter (save the filtrate). Wash the precipitate with a small portion of cold water until free from chloride, and dry at 105° for 4 h.

Acceptance criteria: The dried precipitate meets the requirements.

- B.

Analysis: To the filtrate obtained in *Identification* test A add 0.5 mL of benzenesulfonyl chloride and 5 mL of 1 N sodium hydroxide to render alkaline, shake by mechanical means for 10 min, and add 5 mL of 3 N hydrochloric acid to acidify. Chill, collect the precipitated disulfonamide of ethylenediamine, and wash with water. Recrystallize the washed precipitate from water, and dry at 105° for 1 h.

Acceptance criteria: The dried precipitate melts at 164°–171°.

ASSAY

- **PROCEDURE**

Standard solution: 8 µg/mL of [USP Theophylline RS](#) in dilute hydrochloric acid (1:100)

Sample solution: Pipet a volume of Rectal Solution equivalent to 500 mg of aminophylline into a 500-mL volumetric flask, and dilute with water to volume. Pipet 5 mL of this solution to a second 500-mL volumetric flask, add 50-mL of dilute hydrochloric acid (1:10), and dilute with water to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: About 270 nm

Cell: 1 cm

Blank: Dilute hydrochloric acid (1:100)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of anhydrous theophylline ($C_7H_8N_4O_2$) in the portion of Rectal Solution taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Theophylline RS](#) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

- **CONTENT OF ETHYLENEDIAMINE**

Sample solution: Measure a volume of Rectal Solution, equivalent to 500 mg of aminophylline, and dilute with water if necessary to make 30 mL.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N hydrochloric acid VS

Endpoint detection: Visual

Analysis: Add methyl orange TS to the *Sample solution*, and titrate. Each mL of 0.1 N hydrochloric acid is equivalent to 3.005 mg of ethylene diamine (C₂H₈N₂).

Acceptance criteria: 218–267 mg of ethylenediamine (C₂H₈N₂) per g of theophylline (C₇H₈N₄O₂) found in the Assay

SPECIFIC TESTS

- **pH** (791): 9.0–9.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, single-dose or multiple-dose containers at controlled room temperature.
- **LABELING:** Label the Rectal Solution to state the content of anhydrous theophylline.
- **USP REFERENCE STANDARDS** (11).
[USP Theophylline RS](#)

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

Topic/Question	Contact	Expert Committee
AMINOPHYLLINE RECTAL 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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