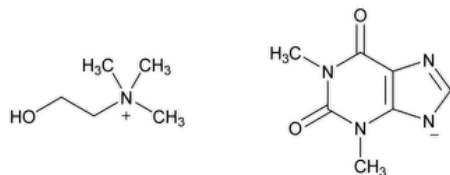


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Oxtriphylline



$C_{12}H_{21}N_5O_3$ 283.33

Ethanaminium, 2-hydroxy-*N,N,N*-trimethyl-, salt with 3,7-dihydro-1,3-dimethyl-1*H*-purine-2,6-dione;

Choline salt with theophylline (1:1) CAS RN®: 4499-40-5; UNII: 3K045XR58X.

DEFINITION

Oxtriphylline contains NLT 61.7% and NMT 65.5% of anhydrous theophylline ($C_7H_8N_4O_2$), calculated on the dried basis.

IDENTIFICATION

• A.

Sample solution: 50 mg/mL in water

Analysis: To 10 mL of the *Sample solution* add 5 mL of mercuric–potassium iodide TS.

Acceptance criteria: A pale yellow precipitate is formed (presence of choline).

• B.

Sample solution: 50 mg/mL in water

Analysis: To 10 mL of the *Sample solution* add 5 drops of 6 N ammonium hydroxide and 5 mL of silver nitrate TS.

Acceptance criteria: A gelatinous precipitate is formed, and it coagulates on heating (presence of theophylline).

ASSAY

• THEOPHYLLINE

Sample solution: The solution retained in the test for *Choline Content*

Analysis: Add 35 mL of silver nitrate TS to the *Sample solution*, and swirl gently to promote complete precipitation. Titrate with 0.1 N sodium hydroxide VS to a green endpoint. Each mL of 0.1 N sodium hydroxide is equivalent to 18.02 mg of theophylline ($C_7H_8N_4O_2$).

Acceptance criteria: 61.7%–65.5% on the dried basis

OTHER COMPONENTS

• CHOLINE CONTENT

Indicator solution: Dissolve 30 mg of methyl red in 100 mL of methanol, and add 15 mL of methylene blue solution (1 in 1000).

Sample solution: 900 mg of Oxtriphylline in 50 mL of water

Analysis: Add 4 drops of *Indicator solution* to the *Sample solution*, and titrate with 0.1 N sulfuric acid VS to a purple endpoint. Each mL of 0.1 N sulfuric acid is equivalent to 12.12 mg of choline ($C_5H_{15}NO_2$). Retain the final solution for the *Assay for Theophylline*.

Acceptance criteria: The content of choline ($C_5H_{15}NO_2$) is between 652 and 693 mg/g of theophylline ($C_7H_8N_4O_2$) found in the *Assay*.

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%

• [CHLORIDE AND SULFATE, Chloride \(221\)](#)

Standard: 0.15 mL of 0.020 N hydrochloric acid

Sample: 0.50 g

Acceptance criteria: 0.02%; the *Sample* shows no more chloride than corresponds to the *Standard*.

• [ORDINARY IMPURITIES \(466\)](#).

Standard solution: Chloroform, alcohol, and formic acid (88:10:2)
Sample solution: Chloroform, alcohol, and formic acid (88:10:2)
Eluant: Chloroform, alcohol, and formic acid (88:10:2)
Visualization: 1
Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE, Class I\(741\)](#): 185°–189°
- [LOSS ON DRYING \(731\)](#)
Analysis: Dry at 80° for 4 h.
Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Oxtriphylline RS](#)

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

Topic/Question	Contact	Expert Committee
OXTRIPHYLLINE	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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