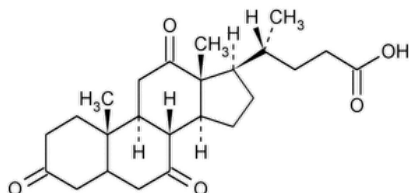


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Dehydrocholic Acid



$C_{24}H_{34}O_5$ 402.52

Cholan-24-oic acid, 3,7,12-trioxo-, (5β)-;

3,7,12-Trioxo-5β-cholan-24-oic acid CAS RN®: 81-23-2; UNII: NH5000009I.

DEFINITION

Dehydrocholic Acid contains NLT 98.5% and NMT 101.0% of $C_{24}H_{34}O_5$, calculated on the dried basis. Dehydrocholic Acid for parenteral use melts between 237° and 242°.

IDENTIFICATION

Change to read:

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

ASSAY

• PROCEDURE

Sample solution: Transfer 500 mg of Dehydrocholic Acid to a 300-mL conical flask, add 60 mL of neutralized alcohol, and warm on a steam bath until dissolved. Allow to cool.

Analysis: Add phenolphthalein TS and 20 mL of water to the *Sample solution*. Titrate with 0.1 N sodium hydroxide VS, adding 100 mL of water shortly before the endpoint is reached. Each mL of 0.1 N sodium hydroxide is equivalent to 40.25 mg of $C_{24}H_{34}O_5$.

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

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

• BARIUM

Sample: 2 g

Analysis: Boil the *Sample* with 100 mL of water for 2 min. Add 2 mL of hydrochloric acid, and again boil for 2 min. Cool, filter, and wash the filter with water until the filtrate measures 100 mL. To 10 mL of the filtrate add 1 mL of 2 N sulfuric acid.

Acceptance criteria: No turbidity is produced.

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 231°–242°, but the range between beginning and end of melting does not exceed 3°.

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#): +29.0° to +32.5°

Sample solution: 20 mg/mL in dioxane

- [LOSS ON DRYING \(731\)](#): Dry at 105° for 2 h: it loses NMT 1.0% of its weight.

- [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): It meets the requirements of the test for absence of *Salmonella* species.

- **ODOR ON BOILING:** Boil 2 g with 100 mL of water for 2 min: the mixture is odorless.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#)
[USP Dehydrocholic Acid RS](#)

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

Topic/Question	Contact	Expert Committee
DEHYDROCHOLIC ACID	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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