Acceptance criteria: See *Table 2*.
[NOTE—The reporting level for impurities is 0.04%.]

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Impurity A*	0.85	•3.0•(RB 1-May-2011)
Deferoxamine	1.0	—
Any unspecified impurity	—	1.0
Total impurities •eluting before deferoxamine•(RB 1-May-2011)	—	5.0
•Total impurities eluting after deferoxamine•(RB 1-May-2011)	—	•2.0•(RB 1-May-2011)

* Des-methylene impurity (desferrioxamine A_1).

SPECIFIC TESTS
- **pH** ⟨**791**⟩**:** 4.0–6.0, in a solution (1 in 100)
- **WATER DETERMINATION,** *Method I* ⟨**921**⟩**:** NMT 2.0%
- **STERILITY TESTS** ⟨**71**⟩**:** Where the label states that Deferoxamine Mesylate is sterile, it meets the requirements.
- **BACTERIAL ENDOTOXINS TEST** ⟨**85**⟩**:** Where the label states that Deferoxamine Mesylate is sterile or must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.33 USP Endotoxin Unit/mg of deferoxamine mesylate.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight containers. Store in a cold place.
- **LABELING:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Deferoxamine Mesylate RS
  USP Endotoxin RS

Deferoxamine Mesylate for Injection

» Deferoxamine Mesylate for Injection contains not less than 90.0 per cent and not more than 110.0 percent of the labeled amount of $C_{25}H_{48}N_6O_8 \cdot CH_4O_3S$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of T ype I glass.

USP Reference standards ⟨11⟩**—**
USP Deferoxamine Mesylate RS
USP Endotoxin RS

Constituted solution—At the time of use, it meets the requirements for *Constituted Solutions* under *Injections* ⟨1⟩.

Identification—It responds to the *Identification* test under *Deferoxamine Mesylate*.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 0.33 USP Endotoxin Unit per mg of deferoxamine mesylate.

pH ⟨791⟩: between 4.0 and 6.0, in a solution (1 in 100).

Water, *Method I* ⟨921⟩: not more than 1.5%.

Other requirements—It meets the requirements under *Injections* ⟨1⟩ and *Uniformity of Dosage Units* ⟨905⟩.

Assay—

Ferric chloride solution and *Standard preparation*—Prepare as directed in the *Assay* under *Deferoxamine Mesylate*.

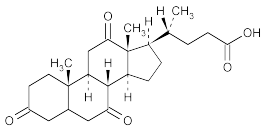
Assay preparation—Constitute the contents of 1 vial in water, and dilute quantitatively, and stepwise if necessar y, with water to obtain a solution having a concentration of about 1 mg per mL.

Procedure—Proceed as directed in the *Assay* under *Deferoxamine Mesylate*. Calculate the quantity, in mg, of deferoxamine mesylate ($C_{25}H_{48}N_6O_8 \cdot CH_4O_3S$) in the vial of Deferoxamine Mesylate for Injection taken by the formula:

$$CV(A_U / A_S)$$

in which C is the concentration, in mg per mL, of USP Deferoxamine Mesylate RS in the *Standard preparation; V* is the volume, in mL, of water used to prepare the *Assay preparation;* and A_U and A_S are the absorbances of the solutions obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Dehydrocholic Acid



$C_{24}H_{34}O_5$ 402.52
Cholan-24-oic acid, 3,7,12-trioxo-, (5 β)-;
3,7,12-Trioxo-5β-cholan-24-oic acid [81-23-2].

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
- **A. INFRARED ABSORPTION** ⟨**197K**⟩

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.
- **HEAVY METALS,** *Method II* ⟨**231**⟩**:** 20 ppm

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

Dehydrocholic Acid Tablets

DEFINITION
Dehydrocholic Acid Tablets contain NLT 94.0% and NMT 106.0% of the labeled amount of $C_{24}H_{34}O_5$.

IDENTIFICATION
- **A. INFRARED ABSORPTION** ⟨**197K**⟩
  Sample: Mix a quantity of finely powdered Tablets equivalent to 500 mg of dehydrocholic acid with 15 mL of water, and add slowly, with stirring, 2 mL of sodium carbonate TS. Filter, and add to the filtrate 3 N hydrochloric acid (about 2 mL) dropwise until no more precipitate is formed. Filter the precipitate, wash with small portions of cold water until free from chloride, and dry at 105° for 2 h. [NOTE—Reserve a portion of the material obtained for use in *Identification* test *B*.]
- **B. MELTING RANGE OR TEMPERATURE** ⟨**741**⟩**:** 231°–242°, but the range between beginning and end of melting does not exceed 3°.
  Sample: Use the material reserved from *Identification* test *A*.

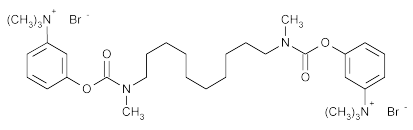
ASSAY
- **PROCEDURE**
  Sample: Finely powder NLT 20 Tablets. Transfer a portion of the powder equivalent to 500 mg of dehydrocholic acid to a 300-mL conical flask. Add 60 mL of neutralized alcohol, and warm on a steam bath for 10 min. Allow to cool.
  Analysis: Add phenolphthalein TS and 20 mL of water. 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: 94.0%–106.0%

PERFORMANCE TESTS
- **DISINTEGRATION** ⟨**701**⟩
  Time: NMT 30 min
- **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements

SPECIFIC TESTS
- **MICROBIAL ENUMERATION TESTS** ⟨**61**⟩ and **TESTS FOR SPECIFIED MICROORGANISMS** ⟨**62**⟩**:** Meets the requirements of the test for absence of *Salmonella* species

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Dehydrocholic Acid RS

Demecarium Bromide



$C_{32}H_{52}Br_2N_4O_4$ 716.59
Benzenaminium, 3,3′-[1,10-decanediylbis[(methylimino)carbonyloxy]]bis[*N*,*N*,*N*-trimethyl]-, dibromide.
(*m*-Hydroxyphenyl)trimethylammonium bromide decamethylenebis[methylcarbamate] (2:1) [56-94-0].

» Demecarium Bromide contains not less than 95.0 percent and not more than 100.5 per cent of $C_{32}H_{52}Br_2N_4O_4$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Demecarium Bromide RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: Dissolve about 100 mg in 50 mL of 1 N sodium hydroxide, and reflux for 15 minutes. Cool, and add 3 mL of the refluxed solution to 25 mL of saturated sodium bicarbonate solution. Add, with mixing, 4 mL of *N*,*N*-dimethyl-*p*-phenylenediamine dihydrochloride solution (1.5 in 10,000) and 2 mL of sodium hypochlorite solution (1.5 in 20,000): a violet-blue color is produced.

C: Dissolve about 50 mg in 20 mL of water, add 10 mL of a 1 in 50 solution of ammonium reineckate in methanol, and allow to stand for 30 minutes with occasional swirling: a pink reineckate of demecarium forms, and it melts between 131° and 136°, with decomposition.

D: A solution of it responds to the tests for *Bromide* ⟨191⟩.

pH ⟨791⟩: between 5.0 and 7.0, in a solution (1 in 100).

Water, *Method I* ⟨921⟩: not more than 2.0%.

Residue on ignition ⟨281⟩: not more than 0.1%.

Heavy metals, *Method I* ⟨231⟩: 0.002%.

Limit of *m*-trimethylammoniophenol bromide—

Control solution—Dissolve 100 mg of *m*-dimethylaminophenol in 10 mL of alcohol in a 1000-mL volumetric flask, dilute with water to volume, and mix. Pipet 1 mL of this solution into a 500-mL volumetric flask, dilute with water to volume, and mix.

Test solution—Transfer 100 mg of Demecarium Bromide to a 100-mL volumetric flask, add water to volume, and mix.

Procedure—Pipet 25 mL of the *Test solution* into a glass-stoppered, 50-mL centrifuge tube, and pipet 25 mL of the *Control solution* into a second, similar tube. To each tube add 3 mL of pH 7.0 phosphate buffer (see under *Solutions* in the section *Reagents, Indicators, and Solutions*), 1 mL of *N*,*N*-dimethyl-*p*-phenylenediamine dihydrochloride solution (1.5 in 10,000), 5 mL of isobutyl alcohol, and 1 mL of sodium hypochlorite solution (1.5 in 20,000). Insert the stoppers in the tubes, shake the mixtures for 5 minutes, and centrifuge: any blue color produced in the upper layer obtained from the *Test solution* is not more intense than that obtained from the *Control solution*.

Assay—Dissolve about 0.8 g of Demecarium Bromide, accurately weighed, in a mixture of 75 mL of glacial acetic acid and 15 mL of mercuric acetate TS, warming slightly, if necessary, to effect solution. Add 2 drops of crystal violet TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 35.83 mg of $C_{32}H_{52}Br_2N_4O_4$.

Demecarium Bromide Ophthalmic Solution

» Demecarium Bromide Ophthalmic Solution is a sterile, aqueous solution of Demecarium Bromide. It contains not less than 92.0 per cent and not more than 108.0 per cent of the labeled amount of $C_{32}H_{52}Br_2N_4O_4$. It contains a suitable antimicrobial agent.