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Dexpanthenol Preparation

DEFINITION

Dexpanthenol Preparation contains NLT 94.5% and NMT 98.5% of dexpanthenol ($C_9H_{19}NO_4$), and NLT 2.7% and NMT 4.2% of pantolactone, both calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F▲ (USP 1-Dec-2021)

Acceptance criteria: The IR absorption spectrum of a thin film of Preparation exhibits maxima only at the same wavelengths as that of USP Dexpanthenol RS, except that there is an additional maximum at 5.6 µm due to pantolactone.

• **B.**

Sample solution: 100 mg/mL of Preparation

Analysis: To 1 mL of the *Sample solution* add 5 mL of 1 N sodium hydroxide and 1 drop of cupric sulfate TS, and shake vigorously.

Acceptance criteria: A deep blue color develops.

COMPOSITION

• **Content of Dexpanthenol**

Sample: 400 mg of Preparation

Blank: Prepare as directed in the *Analysis*, omitting the *Sample*.

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 0.1 N perchloric acid VS

Back titrant: 0.1 M potassium biphthalate prepared as follows. Transfer 20.42 g of potassium biphthalate into a 1000-mL volumetric flask and add sufficient glacial acetic acid to dissolve. If necessary, warm the mixture on a steam bath to achieve complete solution, observing precautions against absorption of moisture. Cool to room temperature, and dilute with glacial acetic acid to volume.

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 300-mL flask fitted to a reflux condenser by means of a standard-taper glass joint, add 50.0 mL of *Titrant*, and reflux for 5 h. Cool, observing precautions to prevent atmospheric moisture from entering the condenser, and rinse the condenser with glacial acetic acid, collecting the rinsings in the flask. Add 5 drops of crystal violet TS to the flask and titrate with the *Back titrant* to a blue-green endpoint. Perform a blank determination.

Calculate the percentage of dexpanthenol ($C_9H_{19}NO_4$) in the *Sample* taken:

$$\text{Result} = \{[(V_B - V_S) \times M \times F]/W\} \times 100$$

V_B = *Back titrant* volume consumed by the *Blank* (mL)

V_S = *Back titrant* volume consumed by the *Sample* (mL)

M = actual molarity of the *Back titrant* (mM/mL)

F = equivalency factor, 205.3 mg/mM

W = weight of the *Sample* (mg)

Acceptance criteria: 94.5%–98.5% on the anhydrous basis

Change to read:

• **Content of Pantolactone**

Internal standard solution: 100 mg/mL of 2,6-dimethylphenol in toluene

Standard stock solution: 10 mg/mL of USP Pantolactone RS in methylene chloride

Standard solution: Pipet 0.4 mL of *Standard stock solution* into a suitable small vial. Evaporate the solvent by means of a steady stream of dry air, and add 50.0 µL of *Internal standard solution*. Add 1 mL of a mixture of pyridine, hexamethyldisilazane, and trimethylchlorosilane (9:3:1), immediately close the vial, and shake vigorously for 30 s.

Sample solution: Transfer 100 mg of Preparation to a suitable small vial and prepare as directed for the *Standard solution*, beginning with "add 50.0 µL of *Internal standard solution*".

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 2.0-mm × 1.8-m; packed with 5% liquid phase G2 on support S1A

Temperatures

▲**Detector:** 180°▲ (USP 1-Dec-2021)

Injection port: 180°

Column: 170°, isothermal

Flow rate: Using a suitable carrier gas, adjust the flow rate so that the derivatized pantolactone elutes in 4 min.

Injection volume: 0.5 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for derivatized pantolactone and derivatized internal standard are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between derivatized pantolactone and the derivatized internal standard

Relative standard deviation: NMT 2.0% for the ratio of the peak response of derivatized pantolactone to the peak response of the derivatized internal standard

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pantolactone in the portion of Preparation taken:

$$\text{Result} = (R_U/R_S) \times (V/W) \times C_S \times 100$$

R_U = internal standard ratio (peak response of derivatized pantolactone/peak response of derivatized internal standard) from the *Sample solution*

R_S = internal standard ratio (peak response of derivatized pantolactone/peak response of derivatized internal standard) from the *Standard solution*

V = volume of the *Standard stock solution* taken to prepare the *Standard solution*, 0.4 mL

W = weight of Preparation taken to prepare the *Sample solution* (mg)

C_S = concentration of USP Pantolactone RS in the *Standard stock solution* (mg/mL)

Acceptance criteria: 2.7%–4.2% on the anhydrous basis

IMPURITIES

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%
- **LIMIT OF AMINOPROPANOL**

Sample: 5 g of Preparation

Blank: 10 mL of water

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N sulfuric acid prepared from 1 N sulfuric acid VS by dilution

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 10 mL of water and add bromothymol blue TS. Titrate with the *Titrant* to a yellow endpoint. Perform a blank determination.

Calculate the percentage of aminopropanol in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 75.11 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

- **Optical Rotation** ⟨781S⟩, *Procedures, Specific Rotation*
  Sample solution: 50 mg/mL in water
  Acceptance criteria: +27.5° to +30.0°
- **Refractive Index** ⟨831⟩**:** 1.495–1.502, at 20°
- **Water Determination** ⟨921⟩, *Method I***:** NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Dexpanthenol RS
  USP Pantolactone RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DEXPANTHENOL PREPARATION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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