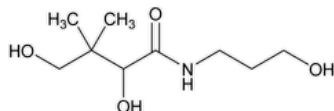


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Panthenol



$C_9H_{19}NO_4$ 205.25

Butanamide, 2,4-dihydroxy-*N*-(3-hydroxypropyl)-3,3-dimethyl-, (±)-;

(±)-2,4-Dihydroxy-*N*-(3-hydroxypropyl)-3,3-dimethylbutyramide;

(±)-Pantothenyl alcohol CAS RN®: 16485-10-2; UNII: WV9CM0067Z.

DEFINITION

Panthenol is a racemic mixture of the dextrorotatory and levorotatory isomers of panthenol. It contains NLT 99.0% and NMT 102.0% of racemic panthenol ($C_9H_{19}NO_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **B.**

Sample solution: 100 mg/mL of Panthenol

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.

• **C.**

Sample solution: 10 mg/mL of Panthenol

Analysis: To 1 mL of the *Sample solution* add 1 mL of 1 N hydrochloric acid, and heat on a steam bath for 30 min. Cool, add 100 mg of hydroxylamine hydrochloride, and add 5 mL of 1 N sodium hydroxide. Allow to stand for 5 min, then adjust with 1 N hydrochloric acid to a pH of 2.5–3.0, and add 1 drop of ferric chloride TS.

Acceptance criteria: A purplish red color develops.

ASSAY

• **PROCEDURE**

0.1 M potassium biphthalate: 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.

Sample: 400 mg of Panthenol

Blank: Proceed 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

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. To the flask add 5 drops of crystal violet TS, and titrate with the *Back-titrant* to a blue-green endpoint. Perform the *Blank* determination.

Calculate the percentage of panthenol ($C_9H_{19}NO_4$) 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/M

W = *Sample* weight (mg)

Acceptance criteria: 99.0%–102.0% on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION** (281): NMT 0.1%

• **LIMIT OF AMINOPROPANOL**

Sample: 10 g of Panthenol

Blank: 25 mL of water

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.01 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 25 mL of water, and add bromothymol blue TS. Titrate with the *Titrant* to a yellow endpoint. Perform the *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 0.10%

SPECIFIC TESTS

• **MELTING RANGE, Class I (741):** 64.5°–68.5°

• **OPTICAL ROTATION, Specific Rotation (781S)**

Sample solution: 50 mg/mL in water

Acceptance criteria: –0.05° to +0.05°

• **LOSS ON DRYING (731):** Dry a sample in a vacuum over phosphorus pentoxide at 56° for 4 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• **USP REFERENCE STANDARDS (11).**

[USP Racemic Panthenol RS](#)

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

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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