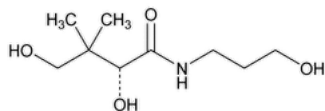


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-EFB17D01-DF55-42CE-98C8-09C88BF866EE_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M23710_02_01
 DOI Ref: 0pik8

© 2025 USPC
 Do not distribute

Dexpanthenol



$C_9H_{19}NO_4$ 205.25

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

D-(+)-2,4-Dihydroxy-*N*-(3-hydroxypropyl)-3,3-dimethyl butyramide CAS RN[®]: 81-13-0; UNII: 106C93RI7Z.

DEFINITION

Dexpanthenol contains NLT 98.0% and NMT 102.0% of dexpanthenol ($C_9H_{19}NO_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

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

• **B.**

Sample solution: 100 mg/mL of Dexpanthenol

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 Dexpanthenol

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 Dexpanthenol

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 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 = *Sample* weight (mg)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%
- **LIMIT OF AMINOPROPANOL**

Sample: 5 g of Dexpanthenol

Blank: 10 mL of water

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 N sulfuric acid VS

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 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 1.0%

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)
Sample solution: 50 mg/mL in water
Acceptance criteria: +29.0° to +31.5°
- [REFRACTIVE INDEX \(831\)](#): 1.495–1.502, at 20°
- [WATER DETERMINATION, Method I \(921\)](#): NMT 1.0%

ADDITIONAL REQUIREMENTS

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

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-EFB17D01-DF55-42CE-98C8-09C88BF866EE_2_en-US

DOI: https://doi.org/10.31003/USPNE_M23710_02_01

DOI ref: [Opik8](#)