# ⟨115⟩ DEXPANTHENOL ASSAY

## INTRODUCTION

The following liquid chromatographic procedure is provided for the determination of dexpanthenol as a component in dietary supplements or pharmaceutical dosage forms.

While conducting this procedure, protect solutions containing and derived from the test specimen and the Reference Standards from the atmosphere and light, preferably with the use of low-actinic glassware. Use the appropriate USP Reference Standards.

## ASSAY

• **Chromatographic Methods, Procedure 1**

This procedure can be used to determine dexpanthenol in:

- *Oil- and Water-Soluble Vitamins Oral Solution*
- *Oil- and Water-Soluble Vitamins with Minerals Oral Solution*
- *Water-Soluble Vitamins with Minerals Oral Solution*

Unless specified in the monograph, the *Standard solution*, *System suitability solution*, and *Sample solution* are prepared as follows.

**Mobile phase:** 0.2 M monobasic sodium phosphate and methanol (97:3). Adjust with 1.7 M phosphoric acid to a pH of 3.2 ± 0.1.

**Standard solution:** 80 µg/mL of USP Dexpanthenol RS in *Mobile phase*

**System suitability solution:** 80 µg/mL of USP Calcium Pantothenate RS in *Mobile phase*. Mix the resulting solution and *Standard solution* (1:1).

**Sample solution:** Equivalent to 80 µg/mL of dexpanthenol from Oral Solution in *Mobile phase*

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 210 nm

**Column:** 4.0-mm × 10-cm; packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

**System suitability**

**Samples:** *Standard solution* and *System suitability solution*

**Suitability requirements**

**Resolution:** NLT 1.5 between dexpanthenol and calcium pantothenate, *System suitability solution*

**Tailing factor:** NMT 2.0 for the dexpanthenol peak, *Standard solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dexpanthenol ($C_9H_{19}NO_4$) in the portion of the sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$ = peak response of dexpanthenol from the *Sample solution*

$r_S$ = peak response of dexpanthenol from the *Standard solution*

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

$C_U$ = nominal concentration of dexpanthenol in the *Sample solution* (mg/mL)

## ADDITIONAL REQUIREMENTS

• **USP Reference Standards** ⟨11⟩

USP Calcium Pantothenate RS

USP Dexpanthenol RS