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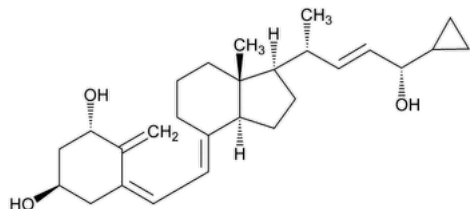
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Calcipotriene

Change to read:


 $C_{27}H_{40}O_3$ 412.60
9,10-Secochola-5,7,10(19),22-tetraene-1,3,24-triol, 24-cyclopropyl-, (1 α ,3 β ,5Z,7E,22E,24S)-;(5Z,7E,22E,24S)-24-Cyclopropyl-9,10-secochola-5,7,10(19),22-tetraene-1 α ,3 β ,24-triol CAS RN[®]: 112965-21-6; UNII: 143NQ3779B.

▲ Monohydrate

 $C_{27}H_{40}O_3 \cdot H_2O$ 430.63 CAS RN[®]: 147657-22-5.▲ (USP 1-May-2021)

DEFINITION

Change to read:

▲ Calcipotriene is anhydrous or contains one molecule of water of hydration. The anhydrous form contains NLT 97.0% and NMT 102.0% of calcipotriene ($C_{27}H_{40}O_3$), calculated on the dried basis. The monohydrate form contains NLT 96.0% and NMT 102.0% of calcipotriene ($C_{27}H_{40}O_3$), calculated on the anhydrous and solvent-free basis.▲ (USP 1-May-2021)

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Protect solutions containing calcipotriene from light and air. Prepare the *Standard solution* and the *Sample solution* NMT 1 h before use.

Prepare the *System suitability solution* daily.

Buffer: 1.0 g/L of tris(hydroxymethyl)aminomethane adjusted with phosphoric acid to a pH of 7.25 $\pm$ 0.25

Mobile phase: Acetonitrile and *Buffer* (45:55)

System suitability solution: 0.1 mg/mL of [USP Calcipotriene RS](#) and 0.01 mg/mL of [USP Calcipotriene Related Compound C RS](#) in *Mobile phase*

Standard solution: 0.1 mg/mL of [USP Calcipotriene RS](#) dissolved in 10% of acetonitrile and then diluted in *Mobile phase*

Sample solution: 0.1 mg/mL of Calcipotriene dissolved in 10% of acetonitrile and then diluted in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 264 nm

Column: 4.0-mm $\times$ 25-cm; 5- μ m packing [L7](#)

Autosampler temperature: 4°

Flow rate: 1.0 mL/min

Injection volume: 20 μ L

System suitability

Samples: *System suitability solution*▲ and *Standard solution*▲ (USP 1-May-2021)

[NOTE—The relative retention times for calcipotriene related compound C and calcipotriene are 0.94 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between calcipotriene related compound C and calcipotriene, ▲*System suitability solution*▲ (USP 1-May-2021)

Relative standard deviation: NMT 1.0%, ▲*Standard solution*▲ (USP 1-May-2021)

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of calcipotriene ($C_{27}H_{40}O_3$) in the portion of Calcipotriene taken:

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

 r_U = peak response of calcipotriene from the *Sample solution* r_S = peak response of calcipotriene from the *Standard solution* C_S = concentration of [USP Calcipotriene RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Calcipotriene in the *Sample solution* (mg/mL)**Acceptance criteria****▲Labeled as anhydrous form:** 97.0%–102.0% on the dried basis**Labeled as monohydrate form:** 96.0%–102.0% on the anhydrous and solvent-free basis ▲ (USP 1-May-2021)**IMPURITIES****Change to read:****• ORGANIC IMPURITIES, PROCEDURE 1: HPLC**Protect solutions containing calcipotriene from light and air. Prepare the *Standard solution* and the *Sample solution* NMT 1 h before use.Prepare the *System suitability solution* daily.**Buffer, Mobile phase, System suitability solution, and Chromatographic system** ▲ (USP 1-May-2021) : Proceed as directed in the Assay.**Standard stock solution:** Use the *Standard solution* in the Assay.**Standard solution:** 0.004 mg/mL of [USP Calcipotriene RS](#) in *Mobile phase*, from the *Standard stock solution***▲Sensitivity solution:** 0.2 µg/mL of [USP Calcipotriene RS](#) in *Mobile phase*, from *Standard solution* ▲ (USP 1-May-2021)**Sample solution:** 0.4 mg/mL of Calcipotriene dissolved in 10% of acetonitrile and then diluted in *Mobile phase***▲System suitability****Samples:** *System suitability solution*, *Standard solution*, and *Sensitivity solution*

[NOTE—The relative retention times for calcipotriene related compound C and calcipotriene are 0.94 and 1.0, respectively.]

Suitability requirements**Resolution:** NLT 1.5 between calcipotriene related compound C and calcipotriene, *System suitability solution***Relative standard deviation:** NMT 5.0%, *Standard solution***Signal-to-noise ratio:** NLT 10, *Sensitivity solution* ▲ (USP 1-May-2021)**Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of any impurity in the portion of Calcipotriene taken:

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

 r_U = peak response of any impurity from the *Sample solution* r_S = peak response of calcipotriene from the *Standard solution* C_S = concentration of [USP Calcipotriene RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Calcipotriene in the *Sample solution* (mg/mL)**Acceptance criteria:** See [Table 1](#). ▲The reporting threshold is 0.05%. ▲ (USP 1-May-2021)**Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
▲Calcipotriene impurity B ^a	0.83	0.5 ▲ (USP 1-May-2021)
Calcipotriene related compound C ^b	0.92–0.96	▲1.0 ▲ (USP 1-May-2021)
Calcipotriene	1.00	