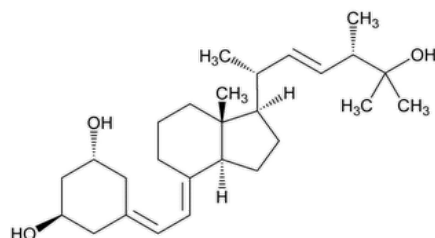


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Paricalcitol



$C_{27}H_{44}O_3$ 416.64

19-Nor-1- α ,25-dihydroxyvitamin D_2 ;

(1 α ,3 β ,7E,22E)-19-Nor-9,10-secoergosta-5,7,22-triene-1,3,25-triol;

(7E,22E)-19-Nor-9,10-secoergosta-5,7,22-triene-1 α ,3 β ,25-triol CAS RN®: 131918-61-1; UNII: 6702D36OG5.

DEFINITION

Paricalcitol contains NLT 97.0% and NMT 103.0% of paricalcitol ($C_{27}H_{44}O_3$), calculated on the dried basis.

[CAUTION—Handle Paricalcitol with exceptional care because it is very potent. Care should be taken to prevent inhaling particles of Paricalcitol and exposing the skin to it.]

IDENTIFICATION

Change to read:

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

PROCEDURE

[NOTE—Protect paricalcitol solutions from light.]

Mobile phase: Methanol and water (4:1)

Diluent: Methanol and water (1:1)

Standard solution: Dilute [USP Paricalcitol Solution RS](#) with *Diluent* to obtain a solution containing 5.0 μ g/mL of paricalcitol.

Sample solution: Transfer an accurately weighed amount of Paricalcitol to a suitable volumetric flask, add dehydrated alcohol (approximately 1 mL of dehydrated alcohol per each 0.5 mg of paricalcitol), sonicate to dissolve, and dilute with *Diluent* to volume. Further dilute this solution with *Diluent* to obtain a solution containing 5.0 μ g/mL of paricalcitol.

Chromatographic system

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

Mode: LC

Detector: UV 252 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing L1

Flow rate: 2 mL/min

Injection volume: 100 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of paricalcitol ($C_{27}H_{44}O_3$) in the portion of Paricalcitol taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of paricalcitol in the *Standard solution* (µg/mL)

C_U = concentration of Paricalcitol in the *Sample solution* (µg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• ORGANIC IMPURITIES

[NOTE—Unless otherwise specified, protect paricalcitol solutions from light.]

Diluent: Dehydrated alcohol and water (50:50)

Solution A: Acetonitrile and water (5:95)

Solution B: Acetonitrile and methanol (75:25)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	42	58
11 ^a	42	58
20	0	100
27	0	100
27.1	42	58
30	42	58

^a Determine the retention time of the paricalcitol peak using the *Standard solution*. Adjust the start of the gradient to be 1.0 ± 0.1 min prior to the retention time of paricalcitol and accordingly adjust the remaining gradient times.

System suitability stock solution: Prepare a 50-µg/mL solution of paricalcitol from [USP Paricalcitol Solution RS](#) in dehydrated alcohol. Using a colorless glass container, expose the solution to ultraviolet light at 254 nm. Paricalcitol undergoes partial degradation to 7Z-paricalcitol. A degradation of at least 0.2% of paricalcitol to 7Z-paricalcitol [(7Z,22E)-19-nor-9,10-secoergosta-5,7,22-triene-1α,3β,25-triol] must be obtained, based on the corresponding peaks. If it is not obtained, expose the solution to ultraviolet light again.

System suitability solution: *System suitability stock solution* and water (1:1)

Standard stock solution: 5 µg/mL of paricalcitol from [USP Paricalcitol Solution RS](#) in *Diluent*

Standard solution: 0.15 µg/mL of paricalcitol from *Standard stock solution* in *Diluent*

Sensitivity solution: 0.05 µg/mL of paricalcitol from *Standard solution* in *Diluent*

Sample stock solution: 200 µg/mL of Paricalcitol in dehydrated alcohol

Sample solution: 100 µg/mL of Paricalcitol from *Sample stock solution* in water

Chromatographic system

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

Mode: LC

Detector: UV 252 nm

Column: 4.6-mm × 10-cm; 2.7-µm packing L1

Column temperature: 30°

Flow rate: 0.9 mL/min