

# Paricalcitol Capsules

**DEFINITION**  
Paricalcitol Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of paricalcitol ( $C_{27}H_{44}O_3$ ). They may contain butylated hydroxytoluene or other suitable antioxidant.

**IDENTIFICATION**  
• **A.** 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.]  
**Solution A:** [Acetonitrile](#), [isopropyl alcohol](#), and [water](#) (50:15:35)  
**Solution B:** [Acetonitrile](#) and [isopropyl alcohol](#) (50:50)  
**Mobile phase:** See [Table 1](#).

Table 1

| Time (min) | Solution A (%) | Solution B (%) |
|------------|----------------|----------------|
| 0          | 100            | 0              |
| 20         | 100            | 0              |
| 21         | 0              | 100            |
| 29         | 0              | 100            |
| 30         | 100            | 0              |
| 35         | 100            | 0              |

**Internal standard solution:** 0.75 µg/mL of [triphenylene](#) in [acetonitrile](#)  
**Standard stock solution:** 10 µg/mL of paricalcitol from [USP Paricalcitol Solution RS](#) in [acetonitrile](#)  
**Standard solution:** A mixture of 0.5 µg/mL of paricalcitol from *Standard stock solution* and 0.15 µg/mL of triphenylene from *Internal standard solution* in [acetonitrile](#)  
**Sample solution:** Nominally 0.5 µg/mL of paricalcitol from Capsules and 0.15 µg/mL of triphenylene from *Internal standard solution*, prepared as follows. Transfer 10 Capsules to a suitable container. Transfer the volume of [acetonitrile](#) specified in [Table 2](#) to a separate beaker. Cut each Capsule to allow the oil to flow freely from the shell. Rinse any tools used to open the shells by pouring in portions of acetonitrile from the beaker into the sample container. When the rinsing is complete, add the remainder of the acetonitrile to the sample container, add the volume of *Internal standard solution* specified in [Table 2](#), and mix well. [NOTE—To facilitate cutting the Capsules open, soften them in a suitable microwave oven for NMT 10 s; taking care not to melt the Capsules. A microwave oven of 600–825 watts was found to be suitable for this procedure.]

Table 2

| Capsule Strength<br>(µg/Capsule) | Volume of Acetonitrile<br>(mL) | Volume of Internal Standard Solution<br>(mL) | Internal Standard Correction Factor<br>(F) |
|----------------------------------|--------------------------------|----------------------------------------------|--------------------------------------------|
| 1                                | 16.0                           | 4.0                                          | 1                                          |
| 2                                | 32.0                           | 8.0                                          | 1                                          |
| 4                                | 65.0                           | 15.0                                         | 0.9375                                     |

**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 252 nm**Column:** 4.6-mm × 25-cm; 5-µm packing L1**Flow rate:** 2.0 mL/min**Injection volume:** 50 µL**Run time:** 20 min**System suitability****Sample:** *Standard solution*

[NOTE—The relative retention times for paricalcitol and triphenylene are 1.0 and 2.0, respectively.]

**Suitability requirements****Resolution:** NLT 4.0 between paricalcitol and triphenylene**Tailing factor:** NMT 2.0 for the paricalcitol peak**Relative standard deviation:** NMT 2.0% for the peak response ratios of paricalcitol to triphenylene**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of paricalcitol ( $C_{27}H_{44}O_3$ ) in the portion of Capsules taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times F \times 100$$

 $R_U$  = peak response ratio of paricalcitol to triphenylene from the *Sample solution* $R_S$  = peak response ratio of paricalcitol to triphenylene from the *Standard solution* $C_S$  = concentration of paricalcitol from [USP Paricalcitol Solution RS](#) in the *Standard solution* (µg/mL) $C_U$  = nominal concentration of paricalcitol in the *Sample solution* (µg/mL) $F$  = internal standard correction factor (see [Table 2](#))**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****• RUPTURE TEST****Apparatus:** Disintegration apparatus with mesh wire, as described in [Disintegration \(701\)](#).**Medium:** [Water](#)

**Procedure:** Preheat disintegration apparatus water bath to  $37 \pm 2^\circ$ . Transfer an appropriate volume of water such that at the highest point of the upward stroke the wire mesh of the basket-rack assembly remains at least 15 mm below the surface of the fluid and descends to NLT 25 mm from the bottom of the vessel on the downward stroke. Place the beakers in the water bath and allow the contents to warm to  $37 \pm 2^\circ$ ; the fluid must be maintained at this temperature for the duration of the test. Place one Capsule in each of the six tubes of the basket-rack assembly, adding a mesh wire screen to each tube, then start the action of the lifting apparatus and timing simultaneously. Observe the units at 5-min intervals.

**Tolerances:** The requirements are met if all of the Capsules tested rupture in NMT 15 min.

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements