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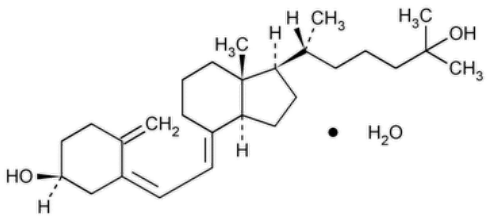
Calcifediol



$C_{27}H_{44}O_2 \cdot H_2O$ 418.65

9,10-Secocholesta-5,7,10(19)-triene-3,25-diol monohydrate, (3β,5*Z*,7*E*)-.

25-Hydroxycholecalciferol monohydrate CAS RN®: 63283-36-3; UNII: P6YZ13C99Q.

» Calcifediol contains not less than 97.0 percent and not more than 103.0 percent of $C_{27}H_{44}O_2 \cdot H_2O$.

Packaging and storage—Preserve in tight, light-resistant containers at controlled room temperature.

USP Reference standards ⟨11⟩—
USP Calcifediol RS

Change to read:

▲**Identification, Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: 197M▲ (CN 1-May-2020)

Water Determination, *Method Ia* ⟨921⟩: between 3.8% and 5.0%, determined on a 0.2-g specimen.

Assay—

Internal standard solution—Dissolve testosterone in ethyl acetate to obtain a solution having a concentration of about 0.10 mg per mL.

Mobile phase—Prepare a suitable degassed solution of about 6 volumes of heptane, 6 volumes of water-saturated heptane, 3 volumes of methylene chloride, and 5 volumes of ethyl acetate.

Standard preparation—Dissolve an accurately weighed quantity of USP Calcifediol RS in *Internal standard solution*, and dilute quantitatively and stepwise with *Internal standard solution* to obtain a solution having a known concentration of about 20 µg per mL.

Assay preparation—Transfer about 10 mg of Calcifediol, accurately weighed, to a 50-mL volumetric flask, dissolve in *Internal standard solution*, dilute with *Internal standard solution* to volume, and mix. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with *Internal standard solution* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 4-mm × 30-cm column that contains packing L3, a detector that monitors absorption at 254 nm, and a pump capable of providing constant flow up to a minimum of 2000 psi.

System suitability—The relative standard deviation for peak response ratios for four replicate injections of *Standard preparation* is not more than 3.0%, and the resolution factor is not less than 3.0.

Procedure—Introduce equal volumes of the *Standard preparation* and the *Assay preparation* into the chromatograph (see *Chromatography* ⟨621⟩), and measure the peak responses obtained. Calculate the quantity, in mg, of $C_{27}H_{44}O_2 \cdot H_2O$ in the portion of Calcifediol taken by the formula:

$$0.5C(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Calcifediol RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak responses of calcifediol to testosterone obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

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Pharmacopeial Forum: Volume No. Information currently unavailable
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