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Calcifediol Capsules

» Calcifediol Capsules contain not less than 90.0 percent and not more than 120.0 percent of the labeled amount of $C_{27}H_{44}O_2 \cdot H_2O$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Calcifediol RS

Identification—Transfer the contents of a number of Capsules, equivalent to about 150 µg of calcifediol, to a suitable container, add 1 mL of methanol, and shake vigorously for 1 minute. Separate the layers by centrifugation, and transfer as much of the top, methanol layer as possible to a second container. Evaporate this extract to dryness, and dissolve the residue in about 1 mL of chloroform. Proceed as directed under *Thin-layer Chromatographic Identification Test ⟨201⟩*, applying 20 µL of this solution and 20 µL of a solution containing about the same concentration of USP Calcifediol RS in chloroform, and using a solvent system consisting of 60 parts of cyclohexane and 40 parts of ethyl acetate.

Dissolution ⟨711⟩—

Medium: water; 500 mL.

Apparatus 2: 50 rpm.

Time: 15 minutes.

Procedure—Place 1 Capsule in each vessel, and allow the Capsule to sink to the bottom of the vessel before starting rotation of the blade. Observe the Capsules, and record the time taken for each capsule shell to rupture.

Tolerances—The requirements are met if all of the Capsules tested rupture in not more than 15 minutes. If 1 or 2 of the Capsules rupture in more than 15 but not more than 30 minutes, repeat the test on 12 additional Capsules. Not more than 2 of the total of 18 Capsules tested rupture in more than 15 but not more than 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Internal standard solution—Dissolve testosterone in ethyl acetate to obtain a solution having a concentration of about 35 µg per mL.

Mobile phase—Prepare as directed in the *Assay* under *Calcifediol*.

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 7 µg of USP Calcifediol RS per mL.

Assay preparation—Transfer a number of Calcifediol Capsules to a suitable container. Using a suitable implement, shear open a number of Capsules inside the container. Wash the implement with an accurately measured volume of *Internal standard solution* that will yield a solution having a concentration of about 7 µg of calcifediol per mL. Collect the rinsings in the container, and mix to obtain a homogeneous solution of the Capsule contents.

Chromatographic system and *System suitability*—Proceed as directed in the *Assay* under *Calcifediol*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Calcifediol*. Calculate the quantity, in µg, of $C_{27}H_{44}O_2 \cdot H_2O$ in the portion of Capsule contents taken by the formula:

$$CV_U(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Calcifediol RS in the *Standard preparation*; V_U is the volume, in mL, of *Internal standard solution* taken for the *Assay preparation*; and R_U and R_S are the peak response ratios 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 CAPSULES	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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