Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-33075335-FC63-4416-89B4-FCF59D647804_3_en-US
DOI: https://doi.org/10.31003/USPNF_M11380_03_01
DOI Ref: z211a

Calcitriol Injection

» Calcitriol Injection is a sterile solution of Calcitriol. It contains an amount of Calcitriol equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of calcitriol ($C_{27}H_{44}O_3$). It contains no antimicrobial agents.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass, protected from light. Store at controlled room temperature.

USP Reference standards ⟨11⟩—
USP Calcitriol Solution RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 100 USP Endotoxin Units per µg of calcitriol.

pH ⟨791⟩**:** between 5.9 and 8.0, determined on a portion to which, if necessary, 0.30 mL of saturated potassium chloride solution has been added for each 100 mL of Injection.

Particulate Matter in Injections ⟨788⟩ **:** meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

[Note—Avoid unnecessary exposure of solutions to light or air.]

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (74:26). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩) so that the retention time for calcitriol is not less than 20 minutes.

Standard preparation—Transfer 3.0 mL of USP Calcitriol Solution RS, equilibrated to room temperature, to a container; add 3.0 mL of water; and mix.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 3 µg of calcitriol, to a container; add a sufficient amount of water to dilute to a total volume of 3.0 mL; add 3.0 mL of methanol; and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 264-nm detector, a 4.6-mm × 4.5-cm guard column that contains 5-µm packing L1, and a 4.6-mm × 7.5-cm analytical column that contains 3-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 100 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of calcitriol ($C_{27}H_{44}O_3$) in each mL of the Injection taken by the formula:

$$C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of calcitriol in the USP Calcitriol Solution RS; and r_U and r_S are the peak responses 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
CALCITRIOL INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 32(1)

Current DocID: GUID-33075335-FC63-4416-89B4-FCF59D647804_3_en-US
Previous DocID: GUID-33075335-FC63-4416-89B4-FCF59D647804_1_en-US
DOI: https://doi.org/10.31003/USPNF_M11380_03_01
DOI ref: z211a