



Certificate of analysis

Product name: **Calcifediol Monohydrate**

Cas number: 63283-36-3

Molecular Formula: C₂₇H₄₆O₃

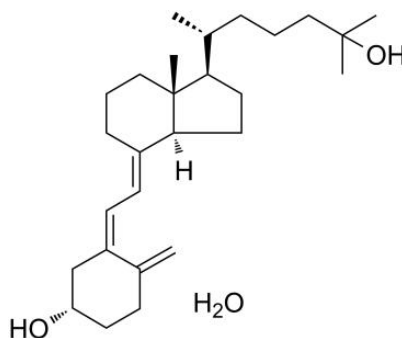
Molecular Weight: 418.65

Date of production: Nov. 23, 2020

Batch NO: 2020123

Exp Date: Nov. 22, 2022

Chemical structure:



Items	Specifications	Results
Appearance	Whiteto or almost white crystalline power	Complies
SOLUBILITY	Practically insoluble in water, freely soluble in 96% alcohol, soluble in fatty oils.	Complies
IDENTIFYCATION	The IR spectrum obtained is in concordance with the reference standard.	Complies
	The principal peak in chromatogram obtained with the test solution is similar in retention time and size to the principal peak in chromatogram obtained with reference solution.	Complies
Related substances	Relative retention: with reference to Calcifediol (retention time = about 11 min) Impurity A = about 1.6 (≤0.5%), Impurity B = about 1.1 (≤0.5%) Impurity C = about 1.2 (≤0.5%) Impurity D = about 0.85 (≤0.5%) Single unspecified impurities (≤0.1% MAX) Total of impurities (≤1.0%)	N.D 0.02% N.D 0.03% N.D 0.05%
Heavy metal	≤10ppm	Complies
Water	3.8%~5.0%	4.11%
Assay	97.0%-102.0%	99.9%



Conclusion: It complies with EP8.0 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F