

Joyochem CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT: CALCIFEDIOL (5Z,7E)-9,10-Secocholesta-5,7,10(19)-triene-3 β ,25-diol monohydrate	DATE OF MANUFACTURE: Jan.24, 2016
PACKING: 1G	DATE OF TEST: Jan.25, 2016
TEST WAYS: EP8.0	EXPIRY DATE: Jan.24, 2017
BATCH NO.: 20160125	

Items	Specifications	Results
Appearance	white or almost white crystals	white crystals
Solubility	practically insoluble in water, freely soluble in ethanol (96 per cent), soluble in fatty oils	Conforms
Identification by IR	The IR spectrum matches reference spectrum of calcifediol.	Conforms
Identification by HPLC	the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution	Conforms
Related substance	Relative retention: with reference to calcifediol (retention time = about 11 min) Impurity A = about 1.6(\leq 0.5%), Impurity B = about 1.1(\leq 0.5%) Impurity C = about 1.2(\leq 0.5%) Impurity D = about 0.85(\leq 0.5%) Single unspecified impurities (\leq 0.1% MAX) Total of impurities (\leq 1.0%)	Not detected 0.03% Not detected 0.04% Not detected 0.07%
Water	3.8% ~ 5.0%	4.22%
Assay	97.0 ~ 102.0% (anhydrous substance)	99.8%

TESTED BY: Lijin

CHECKED BY: Zhangdechen