

Certificate of Analysis

Product name : **Dihydrotachysterol (Ph. Eur./USP)**
 Material : **1000000053**
 Batch : **037507**
 Manufacturing date : **OCT.2019**
 Retest date : **SEP.2022**

Characteristic	Result	Specification
Appearance	complies	colourless crystals or white to almost white crystalline powder
IR spectrum	complies	Corresponds to spectrum of the reference standard
UV spectrum	complies	Corresponds to spectrum of the reference standard
Specific rotation $[\alpha]_{25}^D$ (c=2% m/V in ethanol 96% V/V, in °)	102.0	+100 to +103
residue on ignition, in % m/m	0.05	≤0.1
dihydrovitamin D2-I, in % m/m	<0.54	≤0.5
dihydrovitamin D2-IV, in % rel	0.1	≤0.5
dihydrotachysterol ₄ , in % rel	<0.54	≤0.5
Unspecified, each, in % rel	<0.10	≤0.10
sum of specified and unspecified, in %	0.1	≤1.0
Residual solvents, methanol, in mg/kg	<3000	≤ 3000
Residual solvents, ethanol, in mg/kg	<5000	≤ 5000
Residual solvents, hexanes (calculated as n-hexane), in mg/kg	<290	≤ 290
water (KF), in % m/m	<0.10	≤0.10
Dihydrotachysterol (HPLC), on dry substance, in % m/m	99.6	97.0 - 102.0

This product complies to the specifications of current European Pharmacopoeia and the United States Pharmacopoeia (USP/NF)
 A valid CEP is not available

The batch has been manufactured for CARBOGEN AMCIS B.V. by:
 Dishman Carbogen Amcis Ltd, Survey No. 47, Paiki Sub Plot No. 1 Village-Lodariyal,
 Taluka: Sanand, Ahmedabad 382220, India
 For this site no EUGMP certificate is available

Test results have been taken over of CoA from Dishman Carbogen Amcis Ltd,

G. Takken
 QA Manager



Date: 11-Jun-2021