

500936 Vitamin D3 (cholecalciferol) cryst. (1 g = 40 Mio.I.U.) EMPROVE® ESSENTIAL Ph
Eur,BP,USP



Certificate of Analysis

5.00936.0000 Vitamin D₃ (cholecalciferol) cryst. (1 g = 40 Mio.I.U.) EMPROVE®
ESSENTIAL Ph Eur,BP,USP
Batch K49773636

	Spec. Values			Batch Values	
Assay (HPLC)	97.0 - 102.0	%		100.3	%
Identity (IR-spectrum)	conforms			conforms	
Identity (UV-spectrum (USP))	conforms			conforms	
Spec. rotation [α] ₂₀ /D (8 g/l; (aldehyde-free alcohol 96 %))	+105 - +112	°		+110	°
Spec. rotation [α] ₂₅ /D (5 g/l; ethanol)	+105 - +112	°		+108	°
As (Arsenic)	≤ 3	ppm		≤ 3	ppm
Cu (Copper)	≤ 25	ppm		≤ 25	ppm
Pb (Lead)	≤ 10	ppm		≤ 10	ppm
Zn (Zinc)	≤ 25	ppm		≤ 25	ppm
Acetone (HS-GC)	≤ 5000	ppm		< 5000	ppm
Hexane (HS-GC)	≤ 290	ppm		< 290	ppm
Methanol (HS-GC)	≤ 3000	ppm		< 3000	ppm
Methylformate (HS-GC)	≤ 1000	ppm		< 1000	ppm
Pyridine (HS-GC)	≤ 200	ppm		< 200	ppm
Other residual solvents (ICH Q3C)	excluded by production process			excluded by production process	
Related substances (HPLC) (7,8-didehydrocholesterol)	≤ 0.10	%		≤ 0.10	%
Related substances (HPLC) (trans-cholecalciferol)	≤ 0.1	%		≤ 0.1	%
Related substances (HPLC) (largest unspecified impurity)	≤ 0.10	%		≤ 0.10	%
Related substances (HPLC) (Sum of all impurities)	≤ 1.0	%		≤ 1.0	%

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to Ph Eur, BP, USP

Date of examination (DD.MM.YYYY) 06.12.2017

Minimum shelf life (DD.MM.YYYY) 31.12.2020

Peter Schaub

Responsible laboratory manager quality control

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Eur,BP,USP



Certificate of Analysis

5.00936.0000 Vitamin D₃ (cholecalciferol) cryst. (1 g = 40 Mio.I.U.) EMPROVE®
ESSENTIAL Ph Eur,BP,USP
Batch K49089136

	Spec. Values			Batch Values	
Assay (HPLC)	97.0 - 102.0	%		100.3	%
Identity (IR-spectrum)	conforms			conforms	
Identity (UV-spectrum (USP))	conforms			conforms	
Spec. rotation [α] ₂₀ /D (8 g/l; (aldehyde-free alcohol 96 %))	+105 - +112	°		+110	°
Spec. rotation [α] ₂₅ /D (5 g/l; ethanol)	+105 - +112	°		+108	°
As (Arsenic)	≤ 3	ppm		≤ 3	ppm
Cu (Copper)	≤ 25	ppm		≤ 25	ppm
Pb (Lead)	≤ 10	ppm		≤ 10	ppm
Zn (Zinc)	≤ 25	ppm		≤ 25	ppm
Acetone (HS-GC)	≤ 5000	ppm		< 5000	ppm
Hexane (HS-GC)	≤ 290	ppm		< 290	ppm
Methanol (HS-GC)	≤ 3000	ppm		< 3000	ppm
Methylformate (HS-GC)	≤ 1000	ppm		< 1000	ppm
Pyridine (HS-GC)	≤ 200	ppm		< 200	ppm
Other residual solvents (ICH Q3C)	excluded by production process			excluded by production process	
Related substances (HPLC) (7,8-didehydrocholesterol)	≤ 0.10	%		≤ 0.10	%
Related substances (HPLC) (trans-cholecalciferol)	≤ 0.1	%		≤ 0.1	%
Largest unspecified impurity	≤ 0.10	%		≤ 0.10	%
Sum of all impurities	≤ 1.0	%		≤ 1.0	%

Residues of metal catalysts or metal reagents acc.to EMEA/CHMP/SWP/4446/2000
are not likely to be present.
Corresponds to Ph Eur, BP, USP

Date of examination (DD.MM.YYYY) 22.05.2017
Minimum shelf life (DD.MM.YYYY) 31.05.2020

Peter Schaub
Responsible laboratory manager quality control

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Eur,BP,USP



Certificate of Analysis

5.00936.0000 Vitamin D₃ (cholecalciferol) cryst. (1 g = 40 Mio.I.U.) EMPROVE®
ESSENTIAL Ph Eur,BP,USP
Batch K48684636

	Spec. Values			Batch Values	
Assay (HPLC)	97.0 - 102.0	%		99.3	%
Identity (IR-spectrum)	conforms			conforms	
Identity (UV-spectrum (USP))	conforms			conforms	
Spec. rotation [α] ₂₀ /D (8 g/l; (aldehyde-free alcohol 96 %))	+105 - +112	°		+110	°
Spec. rotation [α] ₂₅ /D (5 g/l; ethanol)	+105 - +112	°		+108	°
As (Arsenic)	≤ 3	ppm		≤ 3	ppm
Cu (Copper)	≤ 25	ppm		≤ 25	ppm
Pb (Lead)	≤ 10	ppm		≤ 10	ppm
Zn (Zinc)	≤ 25	ppm		≤ 25	ppm
Acetone (HS-GC)	≤ 5000	ppm		< 5000	ppm
Hexane (HS-GC)	≤ 290	ppm		< 290	ppm
Methanol (HS-GC)	≤ 3000	ppm		< 3000	ppm
Methylformate (HS-GC)	≤ 1000	ppm		< 1000	ppm
Pyridine (HS-GC)	≤ 200	ppm		< 200	ppm
Other residual solvents (ICH Q3C)	excluded by production process			excluded by production process	
Related substances (HPLC) (7,8-didehydrocholesterol)	≤ 0.10	%		≤ 0.10	%
Related substances (HPLC) (trans-cholecalciferol)	≤ 0.1	%		≤ 0.1	%
Largest unspecified impurity	≤ 0.10	%		≤ 0.10	%
Sum of all impurities	≤ 1.0	%		≤ 1.0	%

Residues of metal catalysts or metal reagents acc.to EMEA/CHMP/SWP/4446/2000
are not likely to be present.
Corresponds to Ph Eur, BP, USP

Date of examination (DD.MM.YYYY) 18.01.2017
Minimum shelf life (DD.MM.YYYY) 31.01.2020

Dr. Christian Urban
Responsible laboratory manager quality control

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