

Certificate of Analysis

Productname: Diclofenacum natricum
Number of analysis/Inspection Code: 1 / KEUR-181167B
Batchnumber: 19L02-F02-367733
Reference code / No.: 3718 / RDS/1908/0264A
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow, crystalline powder	Conform		Slightly hygroscopic
Identification A	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Sodium
Clarity of solution	Helder	Conform		5% <i>m/V</i> in MeOH
Absorbance	<=0,05	Conform		E 440 nm; 5% <i>m/V</i> MeOH
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	0,0	%	
Impurity F	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,4	0,0	%	
Loss on drying	<=0,5	0,1	%	3H 105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Diclofenac sodium	99,0 - 101,0	100,2	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

03/16/20

Expiration: 07-2024

Conclusion: APPROVED

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