

Certificate of Analysis

Product name: **Diclofenacum natricum**

Batch number / Weight: **21I29-B06-217858 / 10 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow, crystalline powder, slightly hygroscopic	Conform		
Melting point	about 280	278,2	°C	
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Clarity of solution	Clear	Conform		
Absorbance	<=0,05	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,2	0,00	%	
Impurity F	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,4	0,00	%	
Loss on drying	<=0,5	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,82	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Agnieszka Pszczółka
 Qualified Person

21-12-2021

Expiration: 31-07-2026

Conclusion: APPROVED

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