

Certificate of Analysis

Product name: **Diclofenacum natricum**

Batch number / Weight: **19L02-F02-217201 / 10 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow, crystalline powder, slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Clarity of solution	Clear	Conform		
Absorbance	$\leq 0,05$	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,2$	0,0	%	
Impurity F	$\leq 0,15$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,4$	0,0	%	
Loss on drying	$\leq 0,5$	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

08-02-2022

Expiration: 31-07-2024

Conclusion: APPROVED

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