

Certificate of Analysis

Product name: **Diclofenacum diethylaminum**

Batch number / Weight: **21I29-B08-218255 / 50 G**

Analysed according to: **British Pharmacopoeia**

Tests	Requirement	Result	Unit	Standard remark
Appearance	A white to light beige, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Clarity of solution	$\leq 0,05$	Conform		
Acid value	6,4 - 8,4	7,68		
Related substances	Conform	Conform		
Any impurity	$\leq 0,2$	$< 0,05$	%	
Total impurities	$\leq 0,5$	0,00	%	
Loss on drying	$\leq 0,5$	0,00	%	
Sulphated ash	$\leq 0,1$	0,005	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Diclofenac diethylamine	99,0 - 101,0	100,11	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

18-05-2022

Expiration: 31-07-2026

Conclusion: APPROVED

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