

Certificate of Analysis

Product name: Diclofenacum natricum
Batch number / Weight: 25D02-B14-015423 / 100 g
Producer / Producer Batch Number: Amoli Organics Pvt. Ltd. / A24370D272
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25D02-B14 / QO0022171

	Requirement	Result	Unit	Standard remark
Appearance	white or slightly yellowish, crystalline powder, slightly hygroscopic	Conform		
Identification	A, D	Conform		
Melting point	About 280	278,4	°C	
Appearance of solution	Clear / absorbance at 440 nm <= 0,05	Conform		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity A	<=0,2	<0,002	%	
Impurity F	<=0,15	<0,002	%	
Any other unspecified impurities	<=0,10	0,02	%	
Total impurities	<=0,4	0,03	%	
Loss on drying	<=0,5	0,13	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	100,40	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE

Release:

30-9-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 30-9-2029

Conclusion: APPROVED

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