Certificate of Analysis

Product name: **Diclofenacum diethylaminum**

Batch number / Weight: **22H17-B02-226871 / 120 G**

Analysed according to: **British Pharmacopoeia**

Number of analysis / Inspection Code **22H17-B02 / INS-22-7091**

Reference Code / No.: **V01389 / A22330D082**

Tests	Requirement	Result	Unit	Standard remark
		1709/S/0822		
Appearance	A white to light beige, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Clarity of solution	<=0,05	Conform		
Acid value	6,4 - 8,4	7,49		
Related substances	Conform	Conform		
Any impurity	<=0,2	<0,05	%	
Total impurities	<=0,5	0,00	%	
Loss on drying	<=0,5	0,00	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Diclofenac diethylamine	99,0 - 101,0	99,97	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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 FAGRON PL lab

Release:
Dominika Sołtysik
Qualified Person

23-01-2023

Expiration: 30-04-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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