Certificate of Analysis

Product name: **Diclofenacum diethylaminum**

Batch number / Weight: **23J09-B12-234308 / 120 G**

Analysed according to: **British Pharmacopoeia**

Number of analysis / Inspection Code **23J09-B12 / INS-23-8657**

Reference Code / No.: **V01389 / A23330D104**

Tests	Requirement	Result	Unit	Standard remark
Appearance	A white to light beige, crystalline powder	Conform		
Identification	Conform	Conform		
Clarity of solution	<=0,05	0,007		
Acid value	6,4 - 8,4	7,74		
Related substances	Conform	Conform		
Any impurity	<=0,2	<0,05	%	
Total impurities	<=0,5	0,00	%	
Loss on drying	<=0,5	0,01	%	
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	99,45	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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:
Agnieszka Pszczółka
Qualified Person

12-01-2024

Expiration: 31-07-2028

Conclusion: APPROVED

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