Certificate of Analysis

Product name: **Ibuprofenum**

Batch number / Weight: **23I21-B02-235149 / 25 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23I21-B02 / INS-23-8138**

Reference Code / No.: **V01417 / C100-2308021M**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	75 - 78	76,3	°C	
Identification C	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Optical rotation	-0,05 - +0,05	-0,044	°	
Related substances	Conform	Conform		
Impurity A	<=0,15	<0,025	%	
Impurity J	<=0,15	0,000	%	
Impurity N	<=0,15	<0,025	%	
Unspecified impurities	<=0,05	0,026	%	
Total impurities	<=0,2	0,03	%	
Impurity F	<=0,1	Conform		
Loss on drying	<= 0,5	0,07	%	
Sulphated ash	<= 0,1	0,01	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Assay	98,5 - 101,0 (dried substance)	99,16	%m/m	

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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, El Spol, CBMiA

Release:
Agnieszka Pszczółka
Qualified Person

30-01-2024

Expiration: 23-08-2028

Conclusion: APPROVED

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