

Certificate of Analysis

Product name: Indometacinum
Batch number / Weight: 23C04-B10-225252 / 10 G
Analysed according to: Ph.Eur.11.1
Number of analysis / Inspection Code 23C04-B10 / INS-23-3012
Reference Code / No.: V01633 / 174221005

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white or yellow powder	Conform		
Identification A	158 - 162	161,5	°C	
Identification C	Conform	Conform		
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	<0,05	%	
Loss on drying	<=0,5	0,13	%	
Sulphated ash	<=0,1	0,00	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 102,0	99,99	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Metallic residues	CHMP/ICH/353369/2013	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, EI Spol

Release:
Dominika Sołtysik
Qualified Person

22-05-2023

Expiration: 07-10-2026

Conclusion: APPROVED

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