

Certificate of Analysis

Product name: Indometacinum
Batch number / Weight: 21H27-B02-213912 / 30 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white or yellow powder	Conform		
Identification A	158 - 162	161	°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	0,03	%	
Sulphated ash	<=0,1	0,05	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 102,0	98,1	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

20-01-2022

Expiration: 05-09-2024

Conclusion: APPROVED

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