

Certificate of Analysis

Productname: Ibuprofenum
Number of analysis/Inspection Code: 1 / KEUR-184902B
Batchnumber: 19A28-B10-369530
Reference code / No.: 4526 / IBD1811306
Analysed according to: PH.EUR 9.7

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder or colourless crystals	Conform		
Identification A	75 - 78	75	°C	
Identification C	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		10 % m/V MeOH
Optical rotation	-0,05 - +0,05	-0,01	°	2.5% m/V MeOH
Related substances	Conform	Conform		HPLC
Impurity A	<=0,15	0,03	%	
Impurity J	<=0,15	<0,03	%	
Impurity N	<=0,15	<0,15	%	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,2	<0,2	%	
Impurity F	<=0,1	Conform	%	GC
Loss on drying	<= 0,5	0,5	%	In vacuo
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Ibuprofen	98,5 - 101,0	100,4	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

08/11/20

Expiration: 10-2023

Conclusion: APPROVED

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