

Certificate of Analysis

Productname: **Allopurinolum**
Number of analysis/Inspection Code: 1 / KEUR-193660B
Batchnumber: **21I06-F02-381003**
Reference code / No.: 4131 / SA0100797
Analysed according to: **PH.EUR10.6**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,1	0,1	%	
Impurity C	<=0,1	0,0	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities other than A,B and C	<=0,3	0,0	%	
Impurity D and E	<=0,1	0,0	%	
Impurity F	<=2,5	0,0	ppm	As hydrazine
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Allopurinol	97,0 - 102,0	100,1	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 Anthony Amoureux
 Qualified Person

02/14/22

Expiration: 07-2026

Conclusion: APPROVED

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