

Certificate of Analysis

Productname:	Allopurinolum		
Number of analysis/Inspection Code:	1 / KEUR-193660B		
Batchnumber:	21106-F02-381003		
Reference code / No.:	4131 / SA0100797		
Analysed according to:	PH.EUR10.6		

Appearance(Almost) white powderConformIR-spectrumIdentification BConformConformIR-spectrumRelade substancesConformConformIPLCImpurity A<=0.20.010\$0.1IPLCImpurity B<=0.10.10\$0.1IPLCUnspecified impurities<=0.100.00\$0.1IPLCSum of impurities other than A,B and<=0.10.00\$0.1IPLCImpurity D and E<=0.10.0\$0.1IPLCImpurity F<=2.50.0ppmAs hydrazineIsola of drying<=0.10.1\$0.1IPLCSulphated ash<=0.10.1\$0.1IPLCAssay Allopurinol<=0.10.0\$1.1IPLCAssay AllopurinolO.1So.10IPLCIPLCTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformIPLAData producerCEPCEP availableCEP availableConformIPLAData producer	Tests	Requirement	Result	Unit	Standard remark
Identification BConformConformIR-spectrumRelated substancesConformConformHPLCImpurity A<=0,2					
Related substancesConformConformHPLCImpurity A<=0,2	Appearance	(Almost) white powder	Conform		
Impurity A<=0,2	Identification B	Conform	Conform		IR-spectrum
Impurity B<=0,10,1%Impurity C<=0,1	Related substances	Conform	Conform		HPLC
Impurity C<=0,10,0%Unspecified impurities<=0,10	Impurity A	<=0,2	<0,05	%	
Unspecified impurities<=0,10<0,05%Sum of impurities other than A,B and C<=0,3	Impurity B	<=0,1	0,1	%	
Sum of impurities other than A,B and C<=0,30,0%Impurity D and E<=0,1	Impurity C	<=0,1	0,0	%	
Impurity D and E<=0,10,0%Impurity F<=2,5	Unspecified impurities	<=0,10	<0,05	%	
Impurity F<=2,50,0ppmAs hydrazineLoss on drying<=0,5	Sum of impurities other than A,B and C	<=0,3	0,0	%	
Loss on drying<=0,50,1%105°CSulphated ash<=0,1	Impurity D and E	<=0,1	0,0	%	
Sulphated ash<=0,10,0%Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformData producerAssay Allopurinol97,0 - 102,0100,1%m/mDriedTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Impurity F	<=2,5	0,0	ppm	As hydrazine
Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformData producerAssay Allopurinol97,0 - 102,0100,1%m/mDriedTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Loss on drying	<=0,5	0,1	%	105°C
Residual solventsCHMP/ICH/82260/2006ConformData producerAssay Allopurinol97,0 - 102,0100,1%m/mDriedTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Sulphated ash	<=0,1	0,0	%	
Assay Allopurinol 97,0 - 102,0 100,1 %m/m Dried TSE/BSE-statement: No contamination with TSE/BSE-risk materials 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	Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
	Assay Allopurinol	97,0 - 102,0	100,1	%m/m	Dried
CEP CEP available Conform Data producer	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 Amoureus Qualified Person

02/14/22

Expiration: 07-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.