



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 225744

Product:	ALLOPURINOL
Lot:	225744
Expiry date:	31/03/2027
Reference:	Cumple PhEur10.8
Synonyms:	Allopurinol.
Formula:	C ₅ H ₄ N ₄ O
Molecular weight:	136,11 g/mol

Assay	Result	Specification	
Identification	Conform(B)	Test PhEur (B)	
Organoleptic properties	Conform	PhEur	
Impurity F	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Loss on drying (105°C)	0,07 %	<= 0,5%	
Sulphated ashes	0,04 %	<= 0,1%	
Assay (HPLC)	100,3 %	97,0-102,0%	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,1 %	
Impurity C	ND	<= 0,1 %	
Unspecified Impurities	ND	<= 0,10 %	
Sum of impurities different from A, B and C	ND	<= 0,3 %	
Impurity D	ND	<= 0,1 %	
Impurity E	ND	<= 0,1 %	
Residual solvent: formamide	<220 ppm	<= 220 ppm	#

Organoleptic characteristics: White or almost white powder. Very slightly soluble in water and in ethanol 96 (per cent). It dissolves in dilute solutions of alkali hydroxides.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 20/01/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00409 HARMAN FINOCHEM LIMITED

Manufacturer batch: SB0101589

Product	Name	Capacity	Batch
1103290	ALOPURINOL	10 g	225744-F-1

1103290	ALOPURINOL	10 g	225744-F-3
1103290	ALOPURINOL	10 g	225744-F-4
1103295	ALOPURINOL	1 kg	225744-P-1
1103296	ALOPURINOL	100 g	225744-J-1
1103296	ALOPURINOL	100 g	225744-J-3
1103296	ALOPURINOL	100 g	225744-J-6
1103296	ALOPURINOL	100 g	225744-J-8
1103297	ALOPURINOL	5 kg	225744-Q-1
1103297	ALOPURINOL	5 kg	225744-Q-2
1370100	ALOPURINOL (FLB)	100 g	225744-J-2
1370100	ALOPURINOL (FLB)	100 g	225744-J-5
1370100	ALOPURINOL (FLB)	100 g	225744-J-7

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

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Date of edition: 20/05/2026

