



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251030**

Product:	ALLOPURINOL
Lot:	251030
Expiry date:	30/07/2027
Reference:	Cumple PhEur11.8
Synonyms:	Allopurinol.
Formule:	C <sub>5</sub> H <sub>4</sub> N <sub>4</sub> O
Poids moléculaire:	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	0,01 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay (HPLC)	98,9 %	97,0-102,0%	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	0,05 %	<= 0,1 %	
Impurity C	ND	<= 0,1 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Sum of impurities different from A, B and C	< 0,05 %	<= 0,3 %	
Impurity D	ND	<= 0,1 %	
Impurity E	ND	<= 0,1 %	
Residual solvent: formamide	< 220 ppm	<= 220 ppm	#
Residual solvent: Triethylamine	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Residual solvent: Dimethyl sulfate	< 1,7 ppm	<= 1,7 ppm	#
Nitrosamine impurities	Conform		#

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: 01/07/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00058 SMS LIFESCIENCES INDIA LIMITED

Manufacturer batch: ALP0050325

Produit	Nom	Capacité	Lot
1103290	ALOPURINOL	10 g	251030-F-1
1103290	ALOPURINOL	10 g	251030-F-2
1103296	ALOPURINOL	100 g	251030-J-1
1103296	ALOPURINOL	100 g	251030-J-3
1103297	ALOPURINOL	5 kg	251030-Q-1
1370100	ALOPURINOL (FLB)	100 g	251030-J-2

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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