



TECHNICAL DATA SHEET

002882-TDS-ENG-2025

ALOPURINOL (EUR. PH.)		
DESCRIPTION DCI: ALLOPURINOL		DESCRIPTION DOE: ALOPURINOL
CAS Nº: 315-30-0	EC Nº: 206-250-9	AEMPS CODE: 318A
MOL. WEIGHT: 136,11	MOL. FORMULA: C ₅ H ₄ N ₄ O	ARTICLE CODE: 002882

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Very slightly soluble in water and in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides.
Identification B	Complies
Related substances	
Impurity A	=< 0.2 %
Impurity B	=< 0.1 %
Impurity C	=< 0.1 %
Unspecified impurities	=< 0.10 %
Sum of impurities other than A, B and C	=< 0.3 %
Impurities D and E	
Impurity D	=< 0.1 %
Impurity E	=< 0.1 %
Impurity F	Complies
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Allopurinol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.