



TECHNICAL DATA SHEET

4643293-TDS-ENG-2024

HIDROXICARBAMIDA (EUR. PH.)		
DESCRIPTION DCI: HYDROXYCARBAMIDE		DESCRIPTION DOE: HIDROXICARBAMIDA
CAS Nº: 127-07-1	EC Nº: 204-821-7	AEMPS CODE: 316A
MOL. WEIGHT: 76,1	MOL. FORMULA: CH4N2O2	ARTICLE CODE: 4643293

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder, hygroscopic
Solubility	Freely soluble in water, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Urea	=< 0.5 %
Related substances	
Any impurity	=< 0.1 %
Total impurities	=< 0.2 %
Chlorides	=< 50 ppm
Water	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Hydroxycarbamide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.