



## TECHNICAL DATA SHEET

1861-TDS-ENG-2021

UREA CRISTAL (PH.EUR)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS N°: 57-13-6	EC N°: ---	AEMPS CODE: ---
MOL. WEIGHT: 60.1	MOL. FORMULA: CH <sub>4</sub> N <sub>2</sub> O	ARTICLE CODE: 1861

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder or transparent crystals, slightly hygroscopic
Solubility	Very soluble in water, soluble in ethanol (96 %), practically insoluble in methylene chloride
Melting point	132 - 135 °C
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
Alcalinity	Complies
Biuret	= < 0.1 %
Ammonium	= < 500 ppm
Loss on drying	= < 1.0 %
Sulfated ash	= < 0.1 %
Assay	98.5 - 101.5 %

### COMPLIES WITH

European Pharmacopoeia 10.0

### STORAGE

Store in a tightly closed container and in a dry place.

### REMARKS

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

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.