



## UREA CRISTAL (EUR. PH.)

PRODUCT CODE: 1861	CAS Nº: 57-13-6	ANALYSIS Nº: 063/25
MANUFACTURER BATCH:	CERTIFICATE ID: 45.539	
SUPPLIER BATCH: W0748604	MANUFACTURING DATE: 05/08/2024	
METAPH BATCH: 0160325	RETEST DATE: 05/08/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder or transparent crystals, slightly hygroscopic	Transparent crystals, slightly hygroscopic (*)
Melting point	132 - 135 °C	134.6 °C (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
Alcalinity	Complies	Complies
Biuret	=< 0.1 %	< 0.1 %
Ammonium	=< 500 ppm	< 500 ppm
Loss on drying	=< 1.0 %	0.06 %
Sulfated ash	=< 0.1 %	< 0.10 %
Assay	98.5 - 101.5 %	98.9 % (*)

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

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

(\*) Data controlled by Metapharmaceutical Industrial SL.

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.

### STORAGE

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

Analysis date: 23/04/2025

Signature: Cristina Borrell Olea (QA/QP)

Conclusion: Complies

Manufacturer: 40000221