

Certificate of Analysis

Product name: **Urea**
Batch number / Weight: **23E08-B01-234250 / 5 KG**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **23E08-B01 / INS-23-4781**
Reference Code / No.: **V01229 / V 126-2022**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification	Conform	Conform		
Identification A	132 - 135	134,72	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Alcalinity	Conform	Conform		
Biuret	<= 0,1	<0,1	%	
Ammonium	<= 500	<500	ppm	
Loss on drying	<=1,0	0,24	%	
Sulphated ash	<= 0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,5 (dried substance)	101,14	%m/m	
E. coli	Negative / gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Own lab

Release:

Ewelina Gadzinowska

Qualified Person

07-11-2023

Expiration: 31-12-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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