

Certificate of Analysis

Product name: Urea
Batch number / Weight: 23E08-B01-235453 / 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 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		
Total aerobic microbial count (TA)	<=10 ³	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	<1	CFU/g	
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 FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

18-12-2023

Expiration: 31-12-2025

Conclusion: APPROVED

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