

HYDROXYCARBAMIDUM 100 g

Lot No.: 23G18-AP23146

Autorisation :	1890IR06261	Date Of Analysis :	18/07/2023
Analytical Reference :	Ph.Eur. (01/2017:1616)	Production Number :	190723-0280623
CNK :	4728-168	Expiry Date :	11/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder, hygroscopic	Complies
Solubility	Freely soluble in water, practically insoluble in ethanol (96%)	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Complies	Complies
Identification B	Complies	Complies
TESTS	SPECIFICATION	RESULT
Urea	≤ 0.5%	< 0.5%
Related substances		
Any impurity	≤ 0.1%	0.02%
Total impurities	≤ 0.2%	0.02%
Chlorides	≤ 50 ppm	< 50 ppm
Water	≤ 0.5%	0.01%
Sulfated ash	≤ 0.1%	0.05%
ASSAY	SPECIFICATION	RESULT
Assay	97.5 – 102.0%	99.1%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: