

# CERTIFICATE OF ANALYSIS

Product : CARBOCISTEINE Ph. Eur. 7

Code: 15192

Batch Nr: 3198

Manufacture: 01/2012

Re-test Date: 01/2017

Client : FAGRON SERVICES B.V.

Shipment (Kg): 300.00

Packs: 6

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	Conforms Ph.Eur.	Conforms
IDENTIFICATION		
.Specific optical rotation	Complies	Conforms
.IR Spectrum	Conforms to St	Conforms
TESTS		
Aspect of solution	Clear and colourless	Conforms
pH	2.8 to 3.0	2.91
Specific optical rotation	-32.5° to -35.5°	-34.4 °
Ninhydrin-positive substances		
.Each impurity	Maximum 0.5 p.cent	< 0.5 p.cent
Chloride	Max 0.15 p.cent (1500ppm)	< 0.15 p.cent
Sulfate	Maximum 300 ppm (0.03%)	< 300 ppm
Heavy metals	Maximum 10 ppm (0.001%)	< 10 ppm
Loss on drying	Maximum 0.5 p.cent	< 0.01 p.cent
Sulfated ash	Maximum 0.3 p.cent	0.04 p.cent
ASSAY		
.Potentiom. (on dried subs.)	98.5 to 101.0 p.cent	100.0 p.cent
ADDITIONAL TESTS		
l-Cysteine	Maximum 0.15 p.cent	Conforms
Zinc	Maximum 10 ppm	Conforms
Phosphates (periodic test)	Maximum 250 ppm (0.025%)	< 250 ppm

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, in the above mentioned site, in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with ICH Q7A.

 Released by QA on 27/01/2012  
 CoA issued on 06/02/2012  
 Signed by Quality Control

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