

MOEHS CATALANA, S.L.

Polígono Rubí Sur

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CERTIFICATE OF ANALYSIS

Product: ACETYLCYSTEINE Ph.Eur. 9

Code: 70250

Batch Nr: 4213

Manufacture: 10/2017

Re-test Date: 10/2022

Customer: METAPHARMACEUTICAL S.L.

Shipment (Kg): 50,00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS Characters	Conforms to Ph. Eur.	Conforms
IDENTIFICATION IR Spectrum	Conforms to Std.	Conforms
Specif. optical rotation (ods)	Complies	Conforms
SPECIFIC TESTS Appearance of solution	Clear and colourless	Conforms
Loss on drying	Maximum 1,0%	0,04 %
pH	2,0 to 2,8	2,26
Specif. optical rotation (ods)	+21,0 to +27,0	24,5
ORGANIC IMPURITIES Related Substances (HPLC)		
L-Cystine	Maximum 0,5%	< 0,05 %
L-Cysteine	Maximum 0,5%	< 0,05 %
N,N'-diacetyl-L-cystine	Maximum 0,5%	0,14 %
N,S-diacetyl-L-cysteine	Maximum 0,5%	< 0,05 %
Any other impurity (biggest)	Maximum 0,10%	< 0,05 %
Total impurities	Maximum 0,5%	0,14 %
INORGANIC IMPURITIES Sulfated ash	Maximum 0,2%	0,08 %
Heavy Metals	Maximum 10 ppm	< 10 ppm
Zinc	Maximum 10 ppm	< 10 ppm
ASSAY Iodometric Assay (on dried subst.)	98,0% to 101,0%	98,5 %

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 Q7, EU GMP Part II and 21 CFR Parts 210 & 211.

Released by QA on 05/02/2018

CoA issued on 16/07/2018

Signed by Quality Control

Pilar Gallego
QC Manager