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**CERTIFICATE OF ANALYSIS**

Code: 15590

Product : ACETYLCYSTEINE Ph. Eur. 8Batch Nr: 4007Manufacture: 02/2016Re-test Date: 02/2021Client : METAPHARMACEUTICAL SLShipment (Kg): 50.00Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	Conforms Ph.Eur.	Conforms
IDENTIFICATION		
.Specific opt. rotation (ods)	Complies	Conforms
.IR Spectrum	Conforms to St	Conforms
TESTS		
Aspect of solution	Clear and colourless	Conforms
pH	2.0 to 2.8	2.24
Specific opt. rotation (ods)	+21.0 to +27.0	23.6
Related substances (HPLC)		
.L-cystine	Maximum 0.5 p.cent	< 0.05 p.cent
.L-cysteine	Maximum 0.5 p.cent	< 0.05 p.cent
.N,N'-diacetyl-L-cystine	Maximum 0.5 p.cent	0.06 p.cent
.N,S-diacetyl-L-cysteine	Maximum 0.5 p.cent	< 0.05 p.cent
.Impurities non ident (biggest)	Maximum 0.10 p.cent	< 0.05 p.cent
.Total Impurities	Maximum 0.5 p.cent	0.06 p.cent
Heavy metals	Maximum 10 ppm (0.001%)	< 10 ppm
Zinc	Maximum 10 ppm	Conforms
Loss on drying	Maximum 1.0 p.cent	0.05 p.cent
Sulfated ash	Maximum 0.2 p.cent	0.15 p.cent
ASSAY		
.Iodometric on dried subs.	98.0 to 101.0 p.cent	100.0 p.cent

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 04/03/2016
CoA issued on 25/10/2016
Signed by Quality Control

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