

## Certificate of Analysis

## Product Description

Acetylcysteine 400  
7323Lot No.: 2867  
Quantity: 1.650 KG

Test Description	Test Results	Specification Limits	Test Method
Appearance	COMPLIES	white crystalline powder	Specific Method
Identification	COMPLIES		
A: Specific rotation	COMPLIES	complies	Ph. Eur. 2.2.7
C: IR spectrum	COMPLIES	complies	Ph. Eur. 2.2.24
Assay	99,8	98,0 - 101,0 % (on dried basis)	Specific Titration
Loss on drying	0,03	NMT 0,5 %	Ph. Eur. 2.2.32
Specific rotation	23,7	+21,0 - +27,0 ° (on dried basis)	Ph. Eur. 2.2.7
Appearance of solution	COMPLIES	clear	Ph. Eur. 2.2.1
Appearance of solution	COMPLIES	colourless	Ph. Eur. 2.2.2 / II
Melting range	104 - 110	104 - 110 °C	Ph. Eur. 2.2.14
pH (1% aq. solution)	2,1	2,0 - 2,6	Ph. Eur. 2.2.3
Sulphated ash	0,03	NMT 0,2 %	Specific Method
Heavy Metals	COMPLIES	NMT 10 ppm	Specific Method
Zinc	COMPLIES	NMT 5 ppm	Ph. Eur. 2.2.25 / II
Related substances	COMPLIES		Ph. Eur. 2.2.29
- L-Cystine	<0,02	NMT 0,1 %	

Page 1/..

The analytical report quoted above is the result of our quality inspection. It does not release the purchaser from the obligation of carrying incoming inspections and it does not mean to assure characteristics features of the product or a fitness for a specific use. An unobjectionable quality is guaranteed in our product specification.

Geschäftsführer: Dr. Oliver Bolzern, Dr. Wolfgang Burger – Sitz der Gesellschaft Rautbling – HRB 16997 – Amtsgericht Traunstein

PharmaZell GmbH  
Rosenheimer Str. 43  
83064 Rautbling  
Tel. +49 (8035) 88 - 0  
Fax +49 (8035) 88 - 143

## Certificate of Analysis

## Product Description

Acetylcysteine 400  
7323Lot No.: 2867  
Quantity: 1.650 KG

- L-Cysteine	<0,01	NMT 0,1 %	
- N,N'-Diacetyl-L-Cystine	<0,03	NMT 0,2 %	
- N,S-Diacetyl-L-Cysteine	<0,01	NMT 0,1 %	
- Max. other impurity	<0,05	NMT 0,10 %	
- Total impurities	<0,07	NMT 0,3 %	
Particle size X10	187	NLT 150 µm	Laser
Particle size X50	285	250 - 425 µm	Laser
Particle size X90	422	LT 530 µm	Laser
Residual solvents	COMPLIES	not present	Ph. Eur. § 4 / USP <467>

Release Date 12.2008  
Retest Date 12.2013

## Reduced testing frequency

Melting range : every 15th production batch

Zinc : every 15th production batch

Statistical quality control evaluation determines these parameters to be within specification limits.

Residual solvents not used in manufacturing process

This lot complies with the requirements of corresponding PharmaZell specification and Ph. Eur. / USP current version

Quality Control Manager  
Dr. Hans-Christian Müller

Report date: 17.12.08

Document generated by computer and valid without signature

Page: 2/2

The analytical report quoted above is the result of our quality inspection. It does not release the purchaser from the obligation of carrying incoming inspections and it does not mean to assure characteristic features of the product or a fitness for a specific use. An unobjectionable quality is guaranteed in our product specification.

Geschäftsführer: Dr. Oliver Bolzern, Dr. Wolfgang Burger – Sitz der Gesellschaft Raubling – HRB 18897 – Amtsgericht Trautheim

PharmaZell GmbH  
Rosenberger Str. 43  
35064 Raubling  
Tel. +49 (0315) 88 - 0  
Fax +49 (0315) 88 - 143