

Certificate of analysis



Article	2001	Acetylcystein, API (Urspr.: Geflügelfedern)	
Synonym		Acetylcysteinum	
Synonym		Acetylcysteine, API (origin:bird feather)	
Batch	23003475		
Specification	Ph.Eur.11.0		
Production date	05.2023	Retest date	05.2028

Test	Specification	Result	
Characters	According to specification	Complies	
Appearance	According to specification	Complies	
Solubility	According to specification	Complies	
Identification	According to specification	Complies	
A	According to specification	Complies	
IR spectrophotometry	According to specification	Complies	
Raman spectrophotometry	According to specification	Complies	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
Specific optical rotation	21.0 ... 27.0	23.4	
Related substances	According to specification	Complies	#
Impurity C	Max. 0.3 %	< 0.2 %	#
Impurity B	Max. 0.2 %	< 0.1 %	#
Impurity D	Max. 0.15 %	< 0.05 %	#
Each unspecified impurity	Max. 0.10 %	< 0.05 %	#
Total of all impurities	Max. 0.5 %	< 0.2 %	#
Zink	Max. 10 ppm	< 10 ppm	#
Loss on drying	Max. 1.0 %	0.0 %	
Sulphated ash	Max. 0.2 %	< 0.1 %	#
Assay	98.5 ... 101.0 %	99.6 %	
Correction factor weighing (f, NRF)	1,000	1,004	
Complies specification		Yes	

Certificate of analysis



Article	2001	Acetylcystein, API (Urspr.: Geflügelfedern)	
Synonym		Acetylcysteinum	
Synonym		Acetylcysteine, API (origin:bird feather)	
Batch	23003475		
Specification	Ph.Eur.11.0		
Production date	05.2023	Retest date	05.2028

Release date	20.12.2023	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Moehs Catalana S.L.		
Manufacturer batch	4884		
Manufacturer street	César Martinelli i Brunet, 12 A		
Manufacturer city	8191 Rubi (Barcelona)		
Manufacturer country	Spanien		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 23003475 complies specification.

This document has been generated automatically and is valid without signature.