



Article	2001	Acetylcystein, API (Urspr.: Geflügelfedern)	
Synonym		Acetylcysteinum	
Synonym		Acetylcysteine, API (origin:bird feather)	
Batch	22001099		
Specification	Ph.Eur.10.3		
Production date	10.2021	Retest date	10.2026

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 %	0,0 %
Impurity B	Max. 0,2 %	0,2 %
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	< 5 ppm
Loss on drying	Max. 1,0 %	0,1 %
Sulphated ash	Max. 0,2 %	0,1 %
Assay	98,5 ... 101,0 %	99,8 %
Correction factor weighing (f, NRF)		1,003
Complies specification		Yes

## Certificate of analysis



---

Article	2001	Acetylcystein, API (Urspr.: Geflügelfedern)	
Synonym		Acetylcysteinum	
Synonym		Acetylcysteine, API (origin:bird feather)	
Batch	22001099		
Specification	Ph.Eur.10.3		
Production date	10.2021	Retest date	10.2026

---

Release date	26.07.2022	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Moehs Catalana S.L.		
Manufacturer batch	4669		
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 22001099 complies specification.

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