

## Certificate of analysis



Article	2053	Benzocain, API	
Synonym		Benzocainum, Aethylum p-aminobenzoicum	
Synonym		Benzocaine, API	
Batch	22002349		
Specification	Ph.Eur.10.1		
Production date	01.2022	Retest date	01.2025

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
IR spectrophotometry	According to specification	Complies
Raman spectrophotometry	According to specification	Complies
Tests	According to specification	Complies
Related substances	According to specification	Complies
Each unspecified impurity	Max. 0,10 %	< 0,05 %
Total of all impurities	Max. 0,2 %	< 0,2 %
Loss on drying	Max. 0,5 %	0,0 %
Sulphated ash	Max. 0,1 %	0,0 %
Assay	99,0 ... 101,0 %	99,7 %
Correction factor weighing (f, NRF)		1,003
Complies specification		Yes

Release date	11.10.2022	Released by	Frau Apoth. Dr. Schlenk, QP, LQK
Manufacturer	Changzhou Sunlight Pharmaceutical Co.Ltd		
Manufacturer batch	C0012201013		
Manufacturer street	216 Yunnan West Road		
Manufacturer city	213134 Benniu Town, Xinbei District, Changzhou		
Manufacturer country	Volksrepublik China **		

GMP-compliant production and testing of the active pharmaceutical ingredients

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

The batch 22002349 complies specification.

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