



Article	2053	Benzocain, API	
Synonym		Benzocainum, Aethylum p-aminobenzoicum	
Synonym		Benzocaine, API	
Batch	24000752		
Specification	Ph.Eur.11.0		
Production date	12.2022	Retest date	12.2025

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 %	0.1 %
Sulphated ash	Max. 0.1 %	< 0.1 %
Assay	99.0 ... 101.0 %	99.4 %
Correction factor weighing (f, NRF)	1,000	1,007
Complies specification		Yes

Release date	10.05.2024	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Changzhou Sunlight Pharmaceutical Co.Ltd		
Manufacturer batch	C0012212007		
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 24000752 complies specification.

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