

Certificate of analysis



Article	2553	Procainhydrochlorid, API	
Synonym		Procaini hydrochloridum	
Synonym		Procaine hydrochloride, API	
Batch	23000279		
Specification	Ph.Eur.10.0		
Production date	10.2022	Retest date	10.2025

Test	Specification	Result	
Characters	According to specification	Complies	
Identification	According to specification	Complies	
Melting point	154 ... 158 °C	156 °C	
IR spectrophotometry	According to specification	Complies	
E	According to specification	Complies	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
pH-Value	5,0 ... 6,5	5,6	
Related substances	According to specification	Complies	#
Loss on drying	Max. 0,5 %	0,2 %	
Sulphated ash	Max. 0,1 %	0,0 %	#
Assay	99,0 ... 101,0 %	100,0 %	#
Correction factor weighing (f, NRF)		1,002	
Complies specification		Yes	

Release date	06.03.2023	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	Chongqing Southwest No.2		
Manufacturer batch	2210001H		
Manufacturer street	No.555,Lanxi Road, Degan Street		
Manufacturer city	402263 Jiangjin District, Chongqing		
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 23000279 complies specification.

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