

Certificate of analysis



Article	2176	Chininhydrochlorid, API	
Synonym		Chinini hydrochloridum	
Synonym		Quinine hydrochloride, API	
Batch	20002720		
Specification	Ph.Eur. 10.0		
Production date	06.2020	Retest date	06.2025

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
Thin-layer chromatography	According to specification	Complies
B	According to specification	Complies
C	According to specification	Complies
D	According to specification	Complies
E	According to specification	Complies
Tests	According to specification	Complies
Appearance of solution	According to specification	Complies
pH-Value	6,0 ... 6,8	6,3
Specific optical rotation	-258 ... -245	-252
Other cinchona alkaloids	According to specification	Complies
Impurity C	Max. 10 %	4 %
Any impurity RT<quinine	Max. 5 %	1 %
Any other impurity	Max. 2,5 %	0,0 %
Sulphates	Max. 500 ppm	< 500 ppm
Barium	According to specification	Complies
Loss on drying	6,0 ... 10,0 %	7,3 %
Sulphated ash	Max. 0,1 %	0,0 %
Assay	99,0 ... 101,0 %	100,4 %
Correction factor weighing (f, NRF)		0,977
Complies specification		Yes

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Production date	06.2020	Retest date	06.2025

Release date	19.11.2020	Released by	Fr. Dr. Haßel
Manufacturer	Buchler GmbH		
Manufacturer batch	9800		
Manufacturer street	Harxbütteler Str. 3		
Manufacturer city	38110 Braunschweig		
Manufacturer country	Deutschland		

GMP-compliant production and testing of the active pharmaceutical ingredients

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

The batch 20002720 complies specification.

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