

Certificate of analysis



Article	5575	Sotalolhydrochlorid, API	
Synonym		Sotaloli hydrochloridum	
Synonym		Sotalol hydrochloride,API	
Batch	23003423		
Specification	Ph.Eur.11.0		
Production date	11.2019	Retest date	10.2024

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
Chloride	According to specification	Complies
Tests	According to specification	Complies
Appearance of solution	According to specification	Complies
pH-Value	4.0 ... 5.0	4.8
Optical rotation	-0.10 ... 0.10	-0.01 °
Related substances	According to specification	Complies
Impurity B	Max. 0.1 %	< 0.1 %
Any other impurity	Max. 0.1 %	< 0.1 %
Total of all impurities	Max. 0.5 %	< 0.1 %
Palladium	Max. 0.5 ppm	< 0.5 ppm
Loss on drying	Max. 0.5 %	0.2 %
Sulphated ash	Max. 0.1 %	0.0 %
Assay	99.0 ... 101.0 %	100.9 %
Correction factor weighing (f, NRF)	1,000	1,002
Complies specification		Yes

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Release date	19.12.2023	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	M/s. Neuland Laboratories Ltd.; Unit-I		
Manufacturer batch	SHI1119112		
Manufacturer street	Temple Road, Gummadidala Mandal		
Manufacturer city	502313 Sangareddy Distict, Telangana		
Manufacturer country	Indien**		

GMP-compliant production and testing of the active pharmaceutical ingredients

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

The batch 23003423 complies specification.

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