Certificate of analysis

Article	5575	Sotalolhydrochlorid, API	
Synonym		Sotaloli hydrochloridum	
Synonym		Sotalol hydrochloride,API	
Batch	24002039		
Specification	Ph.Eur.11.3		
Production date	06.2024	Retest date	05.2029

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
Related substances	According to specification	Complies
Impurity A	Max. 0.3 %	0.0 %
Each unspecified impurity	Max. 0.10 %	0.06 %
Total of all impurities	Max. 0.5 %	0.1 %
Loss on drying	Max. 0.5 %	0.1 %
Sulphated ash	Max. 0.1 %	0.0 %
Assay	99.0 ... 101.0 %	100.2 %
Correction factor weighing (f, NRF)	1,000	1,001
Complies specification		Yes

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Production date	06.2024	Retest date	05.2029

Release date	21.11.2024	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	M/s. Neuland Laboratories Ltd.; Unit-I		
Manufacturer batch	SHI0624053		
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 24002039 complies specification.

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