

Certificate of analysis



Article	2553	Procainhydrochlorid, API
Synonym		Procaini hydrochloridum
Synonym		Procaine hydrochloride, API
Batch	150069	
Specification	PH.EUR. 8.0	
Expiry date	11.2017	

Test	Specification	Result
Characters	In accordance	Complies
Identification	In accordance	Complies
-Melting point	154 - 158 °C	155,9 °C
-IR spectrophotometry	In accordance	Complies
-F	In accordance	Complies
Tests	In accordance	Complies
-Appearance of solution	In accordance	Complies
-pH	5,0 - 6,5	5,59
-Related substances	In accordance	Complies #
-Heavy metals	Max 5 ppm	Max 5 ppm #
-Loss on drying	Max 0,5 %	0,00 %
-Sulphated ash	Max 0,1 %	Max 0,1 % #
Assay	99,0 - 101,0 %	100,00 % #
Correction factor weighing (f, NRF)	*****	1,000
Complies specification	*****	Yes

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Test	Specification	Result
GMP-conform		
Release date	09.02.2015	Head of Quality Control
Manufacturer	Norbrook s.r.o.	Fr. Dr.Haßel
Manufacturer Batch	1821212	
Manufacturer City	53354 Rybitví RY 133	
Manufacturer street	Pardubice 20	
Manufacturer Country	Tschechien	

Result taken from the manufacturer's certificate

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