

Certificate of analysis



Article	4560	Propranololhydrochlorid, API	
Synonym		Propranololi hydrochloridum	
Synonym		Propranolol hydrochloride, API	
Batch	23003559		
Specification	Ph.Eur.11.0		
Production date	08.2022	Retest date	07.2027

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
Melting point	163 ... 166 °C	165 °C
IR spectrophotometry	According to specification	Complies
D	According to specification	Complies
Tests	According to specification	Complies
Appearance of solution	According to specification	Complies
Acidity or alkalinity	According to specification	Complies
Related substances	According to specification	Complies
Each unspecified impurity	Max. 0.10 %	< 0.10 %
Total of all impurities	Max. 0.2 %	0.0 %
Loss on drying	Max. 0.5 %	0.0 %
Sulphated ash	Max. 0.1 %	< 0.1 %
Assay	99.0 ... 101.0 %	100.5 %
Correction factor weighing (f, NRF)	1,000	1,000
Complies specification		Yes

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Release date	01.03.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	IPCA Laboratories Limited		
Manufacturer batch	22131PRRII		
Manufacturer street	P.O. Sejavta		
Manufacturer city	457 001 District - Ratlam (M.P.)		
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 23003559 complies specification.

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