

Certificate of analysis



Article	2224	Ephedrinhydrochlorid, API	
Synonym		Ephedrinum hydrochloricum plv.	
Synonym		Ephedrine hydrochloride, API	
Batch	24000466		
Specification	Ph.Eur.11.0		
Production date	01.2023	Retest date	01.2027

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	
E	According to specification	Complies	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
Acidity or alkalinity	According to specification	Complies	
Specific optical rotation	-35.5 ... -33.5	-33.6	
Related substances	According to specification	Complies	#
Impurity A	Max. 0.2 %	< 0.1 %	#
Each unspecified impurity	Max. 0.1 %	< 0.1 %	#
Total of impurities other than A	Max. 0.5 %	< 0.1 %	#
Sulphates	Max. 100 ppm	< 100 ppm	#
Loss on drying	Max. 0.5 %	0.1 %	
Sulphated ash	Max. 0.1 %	< 0.1 %	#
Assay	99.0 ... 101.0 %	99.6 %	#
Correction factor weighing (f, NRF)	1,000	1,005	
Complies specification		Yes	

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Production date	01.2023	Retest date	01.2027

Release date	06.03.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	Siegfried PharmaChemikalien Minden GmbH		
Manufacturer batch	23022087		
Manufacturer street	Karlstrasse 15-39, 42-44		
Manufacturer city	32423 Minden		
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 24000466 complies specification.

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