

Certificate of analysis



Article	5351	Mupirocin-Calcium, mikronisiert, API (mikrob. Herkunft)	
Synonym		Mupirocinum calcicum	
Synonym		Mupirocin-Calcium, micronized, API(microbial origin)	
Batch	23003561		
Specification	Ph.Eur.11.0		
Production date	10.2022	Retest date	09.2027

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	
B	According to specification	Complies	
Tests	According to specification	Complies	
Specific optical rotation	-20 ... -16	-18	
Related substances	According to specification	Complies	#
Impurity C	Max. 2.5 %	0.9 %	#
Any other impurity	Max. 1 %	< 1 %	#
Total of all impurities	Max. 4.5 %	1.9 %	#
Chlorides	Max. 0.5 %	< 0.5 %	#
Water	3.0 ... 4.5 %	3.6 %	
Assay (anhydrous substance)	93.0 ... 102.0 %	99.4 %	
Correction factor weighing (f, NRF)	1,000	1,009	
Complies specification		Yes	
Teilchengröße < 100 µm	Entspricht, Nicht durchgeführt	Corresponds to	

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Release date	02.02.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	TEVA Pharmaceutical Works Private Limite		
Manufacturer batch	83200340122		
Manufacturer street	Pallagi ut 13		
Manufacturer city	4042 Debrecen		
Manufacturer country	Ungarn		

GMP-compliant production and testing of the active pharmaceutical ingredients

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

The batch 23003561 complies specification.

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