Certificate of analysis

Article	5340	Mometasonfuroat, mikronisiert, API
Synonym		Mometasoni furoas
Synonym		Mometasone furoate, micronized, API
Batch	24002020	
Specification	Ph.Eur.11.0	
Production date	04.2024	Retest date 03.2028

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
HPLC	According to specification	Complies
E	According to specification	Complies
Tests	According to specification	Complies
Specific optical rotation	50 ... 55	52
Related substances	According to specification	Complies
Impurity J	Max. 0.15 %	< 0.05 %
Each unspecified impurity	Max. 0.10 %	< 0.05 %
Total of all impurities	Max. 0.3 %	0.0 %
Loss on drying	Max. 0.5 %	0.1 %
Assay	98.0 ... 102.0 %	99.8 %
Correction factor weighing (f, NRF)	1,000	1,003
Complies specification		Yes
Intern		

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Release date	07.10.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	Halcyon Labs Pvt. Ltd.		
Manufacturer batch	HMF00324		
Manufacturer street	Plot No. 409, Phase- IV, GIDC Estate,		
Manufacturer city	Naroda, Ahmedabad- 382 330		
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 24002020 complies specification.

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