

Certificate of analysis



Article	4207	Dexamethasonacetat, mikronisiert, API	
Synonym		Dexamethasoni acetas	
Synonym		Dexamethasone acetate, micronized, API	
Batch	24000144		
Specification	Ph.Eur.11.0		
Production date	01.2023	Retest date	01.2026

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
Tests	According to specification	Complies
Specific optical rotation	94 ... 99	96
Related substances	According to specification	Complies
Impurity I	Max. 0.4 %	0.0 %
Impurity D	Max. 0.3 %	0.0 %
Impurity A	Max. 0.2 %	< 0.1 %
Impurity E	Max. 0.2 %	0.0 %
Each unspecified impurity	Max. 0.10 %	< 0.01 %
Total of all impurities	Max. 0.5 %	0.1 %
Loss on drying	Max. 0.5 %	0.0 %
Assay	97.5 ... 102.0 %	99.0 %
Correction factor weighing (f, NRF)	1,000	1,010
Complies specification		Yes

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Production date	01.2023	Retest date	01.2026

Release date	12.01.2024	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Tianjin Tianyao Pharmaceuticals Co.Ltd		
Manufacturer batch	NDAC230107		
Manufacturer street	NO.19, Xinye 9th Street, West Area of		
Manufacturer city	300462 Tianjin		
Manufacturer country	Volksrepublik China **		

GMP-compliant production and testing of the active pharmaceutical ingredients

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

The batch 24000144 complies specification.

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