

Certificate of analysis



Article	2483	Estradiol-Hemihydrat, mikronisiert, API	
Synonym		17beta-Estradiol	
Synonym		Estradiol hemihydrate, micronized, API(microbial origin)	
Batch	23000120		
Specification	Ph.Eur.10.0		
Production date	09.2022	Retest date	09.2026

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
Tests	According to specification	Complies
Specific optical rotation	76,0 ... 83,0	79,5
Related substances	According to specification	Complies
Impurity A	Max. 0,3 %	< 0,1 %
Impurity B	Max. 0,3 %	< 0,1 %
Impurity C	Max. 0,3 %	< 0,1 %
Impurity D	Max. 0,3 %	< 0,1 %
Each unspecified impurity	Max. 0,10 %	< 0,05 %
Total of all impurities	Max. 0,5 %	< 0,1 %
Water	2,9 ... 3,5 %	3,3 %
Assay	97,0 ... 103,0 %	97,1 %
Correction factor weighing (f, NRF)		1,031
Complies specification		Yes

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Release date	03.03.2023	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	La Chandra Pharmalab Pvt. Ltd.		
Manufacturer batch	ESDC-22001M2		
Manufacturer street	Tal Dantiwada		
Manufacturer city	Dist.-Banaskantha, Gujarat - 385510		
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 23000120 complies specification.

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