

Minoxidil

CODE ARTICLE: 93797	BATCH: 0133978	Active pharmaceutical ingredient
TEST DATE: 20/01/2025	TEST: QC-00271703	
EXPIRY DATE: 30/07/2029	FABRICATION DATE: 01/08/2024	MR: 209,30
CAS: [38304-91-5]	FORMULA: C9H15N5O	
SYNONYMS / BOTANICAL NAME: Minoxidilo		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			White or almost white crystal powder	PH.EUR.*
COLOUR	PASS -			WHITE	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	PROPYLENE GLYCOL				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	PASS				PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	N.D. %			<=0,3	PH.EUR.*
OTHER IMPURITIES	N.D. %			<=0,10	PH.EUR.*
IMPURITY B	N.D. %			<=0,15	PH.EUR.*
IMPURITY E	N.D. %			<=0,2	PH.EUR.*
LOSS ON DRYING	0,1 %			<=0,5	PH.EUR.*
SULPHATED ASHES	0,01 %			<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100 %		99	101	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	<3000 ppm			<=500	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS -				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS -				Manufacture's Standard

NON-sterile



Silvia Sancho-Tello Ripoll
Technical Director.

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 55786 K.O.P. LIMITED (India) Manufacturer Batch: K007.2/24/08/381 Manufacturer original CoA available under request

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