

Certificate of Analysis

Minoxidil

CODE ARTICLE: 93797		BATCH: 0132434	Active pharmaceutical ingredient			
TEST DATE: 27/11/2024		TEST: QC-00270309				
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 c	ool, dry place.					

TEST	RESULTS Units	MIN	MAX	METHOD
APPEARANCE	PASS -		White or almost white crystal powder	PH.EUR.*
COLOUR	PASS -		WHITE	PH.EUR.*
SOLUBILITY				
SOLUBLE	METHANOL			PH.EUR.*
SOLUBLE	PROPYLENE GLYCOL			PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN WATER			PH.EUR.*
<u>IDENTIFICATION</u>				
IR IDENTIFICATION	PASS			PH.EUR.*
RELATED SUBSTANCES				
TOTAL IMPURITIES	<loq=0,05% %<="" td=""><td></td><td><=0,3</td><td>PH.EUR.*</td></loq=0,05%>		<=0,3	PH.EUR.*
OTHER IMPURITIES	<loq=0,05% %<="" td=""><td></td><td><=0,10</td><td>PH.EUR.*</td></loq=0,05%>		<=0,10	PH.EUR.*
IMPURITY B	<loq=0,05% %<="" td=""><td></td><td><=0,15</td><td>PH.EUR.*</td></loq=0,05%>		<=0,15	PH.EUR.*
IMPURITY E	<loq=0,05% %<="" td=""><td></td><td><=0,2</td><td>PH.EUR.*</td></loq=0,05%>		<=0,2	PH.EUR.*
LOSS ON DRYING	0,04 %		<=0,5	PH.EUR.*
SULPHATED ASHES	0,04 %		<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,8 %	99	101	PH.EUR.*
RESIDUAL SOLVENTS				
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

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

Silvia Sancho-Tello Ripoll Technical Director.

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.

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