

Minoxidil

CODE ARTICLE: 93797	BATCH: 0125831	Active pharmaceutical ingredient
TEST DATE: 24/10/2023	TEST: QC-00257908	
EXPIRY DATE: 30/10/2028	FABRICATION DATE: 01/10/2023	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	CONFORM	-		White or almost white crystal powder	PH.EUR.*
COLOUR	CONFORM	-		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	CONFORM				PH.EUR.*
MELTING POINT	253 °C		248	268	USP
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	<RT=0,05 %			<=0,3	PH.EUR.*
OTHER IMPURITIES	<RT=0,05 %			<=0,10	PH.EUR.*
IMPURITY B	<RT=0,05 %			<=0,15	PH.EUR.*
IMPURITY E	<RT=0,05 %			<=0,2	PH.EUR.*
LOSS ON DRYING	0,04 %			<=0,5	PH.EUR.*
SULPHATED ASHES	0,02 %			<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,6 %		99	101	PH.EUR.*
DENSITY	0,5 G/ML		0,4	0,6	Manufacture's Standard
PARTICLE SIZE < 125	100 %		100		Manufacture's Standard
PARTICLE SIZE <100	96,3 %		90		Manufacture's Standard
<u>RESIDUAL SOLVENTS</u>					
METHANOL	30 ppm			<=500	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM	-			Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM	-			Manufacture's Standard
<u>NON-sterile</u>					

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: 45023 T. S.P.A. (Italia) Manufacturer Batch: 323059 Manufacturer original CoA available under request

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

Silvia Sancho-Tello Ripoll
Technical Director.

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