METAPHARMACEUTICAL IND SL
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MINOXIDIL (EUR. PH.)

PRODUCT CODE: 1301	CAS Nº: 38304-91-5	ANALYSIS Nº: 257/24	
MANUFACTURER BATCH:	0024201942	CERTIFICATE ID:	43.708
SUPPLIER BATCH:	----	MANUFACTURING DATE:	04/07/2024
METAPH BATCH:	0101024	RETEST DATE:	01/05/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification B	Complies	Complies
Related substances		
Impurity E	=< 0.2 %	< 0.2 %
Impurity B	=< 0.15 %	< 0.15 %
Unspecified impurities	=< 0.10 %	< 0.10 %
Total impurities	=< 0.3 %	< 0.3 %
Loss on drying	=< 0.5 %	0.06 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	99.0 - 101.0 %	100.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Minoxidil is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

Analysis date: 26/02/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000353
OLON s.p.a.
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26837 Mulazzano
Lodi(Itàlia)