

**MINOXIDIL (EUR. PH.)**

PRODUCT CODE: 1301	CAS N°: 38304-91-5	ANALYSIS N°: 155/23
MANUFACTURER BATCH: 2320001134	CERTIFICATE ID: 38.534	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 26/04/2023	
METAPH BATCH: 0380523	RETEST DATE: 15/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	white or almost white, crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, soluble in methanol and in propylene glycol	Complies (*)
Identification B	Complies	Complies
Related substances		
Impurity E	=< 0.2 %	< 0.05 %
Impurity B	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	< 0.05 %
Loss on drying	=< 0.5 %	0.07 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	99.0 - 101.0 %	100.5 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

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

(\*) Data adapted from the manufacturer's certificate of analysis.

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: 14/07/2023  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000353  
OLON s.p.a.  
Stabilimento di Garbagnate Milanese  
Via Milano, 186  
20024 Garbagnate Milanese (MI)