



TECHNICAL DATA SHEET

010916-TDS-ENG-2024

MINOXIDIL (EUR. PH.) (WHO-GMP)		
DESCRIPTION DCI: MINOXIDIL		DESCRIPTION DOE: MINOXIDIL
CAS Nº: 38304-91-5	EC Nº: 253-874-2	AEMPS CODE: 782A
MOL. WEIGHT: 209,25	MOL. FORMULA: C ₉ H ₁₅ N ₅ O	ARTICLE CODE: 010916

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.