

Lot: 0100524



Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2020003287
Batch Size 430,000 KG

546

Manufacturing date 03/12/2020
Re-test date 03/04/2024
Certificate Nr. 890000007276

Test	References	Specification	M.U.	Result
Appearance	EP	White or almost white crystalline powder		Almost white crystalline powder
Identification (IR)	EP (2.2.24)/USP <197	IR spectrum conforms to standard		Complies
Identification (HPLC)	M> USP	Complies		Complies
Loss on drying	EP 2.2.32	<=0,5	%	0,16
Residue on ignition	EP 2.4.14 USP < 281	<=0,1	%	0,07
Appearance of solution Y6	EP(2.2.1)/(2.2.2)	Clear and not more coloured than Y6		Clear and not more coloured than
Related substances (HPLC): 2,4-diamine-6-chloropyrimidine (Impurity B) + 2,4-diamino-5,6-dichloropyrimidine-3-oxide	EP 2.2.29	<=0,10	%	< LOD (0,004)
Related substances (HPLC): 2,4-Diamine-6-Piperidinopyrimidine (impurity E or deoxyminoxidil)	EP 2.2.29	<=0,2	%	< LOD (0,007)
Related substances (HPLC): unspecified impurities	EP 2.2.29	<=0,10	%	< LOQ (0,020)
Related substances (HPLC): total impurities by EP	EP 2.2.29	<=0,3	%	0,014
Organic impurities (HPLC): Pyrimidine oxide analog	USP	<=0,2	%	< 0,05
Organic impurities (HPLC): Pyrimidine analog	USP	<=0,2	%	< 0,05
Organic impurities (HPLC): Deoxyminoxidil	USP	<=0,2	%	0,18
Organic impurities (HPLC): Any individual unspecified impurity	USP	<=0,1	%	0,09
Organic impurities (HPLC): Total impurities by USP	USP	<=0,3	%	0,28
Assay (HPLC)	USP	97,0 - 103,0	%	99,2

Angelo Cavicchioli
QC Manager
Approved April 22, 2021

Donatella Magani
Qualified Person
Approved April 22, 2021



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(on dried basis)				
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	100,7
Residual solvents (GC): acetone	Internal Method	<= 1000	ppm	< LOQ (50)
Residual solvents (GC): Isopropyl Alcohol	Internal Method	<= 2000	ppm	< LOQ (100)
Particle size	Internal Method	On customer request		On customer request

This batch was manufactured, packaged and tested in compliance with ICH Q7 and EU GMP Guideline Volume 4 Part II.

Manufacturing site of the Active Pharmaceutical Ingredient: Olon spa Mulazzano Plant.

Not to be used in sterile parenteral and sterile non-parenteral products.

Angelo Cavicchioli
QC Manager
Approved April 22, 2021

Donatella Magani
Qualified Person
Approved April 22, 2021

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640
Società Capogruppo P. & R. Principi Attivi S.p.A
Società con Socio unico - Strada Rivoltana km. 6/7 - 20053 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v. - C.F. e P.IVA 11155530964

Modello: 17150-STD / 5

April 22, 2021

This CoA is electronically dated and signed by authorized personnel of the Quality Unit

April 22, 2021

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