

METAPHARMACEUTICAL

N DE LOTE:

0380523

Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2320001134
Order 1230757
Quantity 350,000 KG

Manufacturing date 26/04/2023
Re-test date 15/04/2028
Certificate Nr. 100000028236
Batch Size 845,000 KG
Ref. Order 2023-1/192

df 30/05/2023

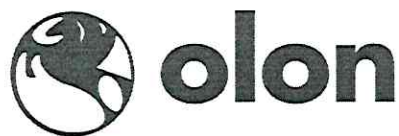
Test	References	Specification	M.U.	Result
Appearance	EP	White crystalline powder		White crystalline powder
Identification (IR)	EP (2.2.24)/USP <197	IR spectrum conforms to standard		Complies
Identification (HPLC)	M> USP	Complies		Complies
Loss on drying	EP 2.2.32	<= 0,50	%	0,01
Residue on ignition	EP 2.4.14 USP < 281	<= 0,10	%	0,10
Appearance of solution Y6	EP(2.2.1)/(2.2.2)	Clear and not more colour ed 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	<= 0,100	%	< LOD (0,004)
Related substances (HPLC): 2,4-Diamine-6-Piperidinpyrimidine (impurity E or deoxyminoxidil)	EP 2.2.29	<= 0,20	%	< LOD (0,007)
Related substances (HPLC): unspecified impurities	EP 2.2.29	<= 0,100	%	< LOQ (0,020)
Related substances (HPLC): total impurities by EP	EP 2.2.29	<= 0,300	%	0,029
Organic impurities (HPLC): Pyrimidine oxide analog	USP	<= 0,20	%	< LOQ (0,008)
Organic impurities (HPLC): Pyrimidine analog	USP	<= 0,20	%	< LOD (0,002)
Organic impurities (HPLC): Deoxyminoxidil	USP	<= 0,20	%	< LOD (0,013)
Organic impurities (HPLC): Any individual unspecified impurity	USP	<= 0,10	%	< LOQ (0,022)
Organic impurities (HPLC): Total impurities by USP	USP	<= 0,30	%	0,01
Assay (HPLC) (on dried basis)	USP	97,0 - 103,0	%	99,2

Silvana Zanetta	Laura Berra Qualified Person		
Approved May 19, 2023	Released May 19, 2023		
Customer specification	Silvana Zanetta		May 19, 2023
Approved	Laura Berra	Qualified Person	May 19, 2023
'Emission'	Dario Bertolo	QA Specialist	May 23, 2023

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



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<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	100,0
Residual solvents (GC): acetone	Internal Method	<= 1000	ppm	< LOD (25)
Residual solvents (GC): Isopropyl Alcohol	Internal Method	<= 2000	ppm	< LOD (45)
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.

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