

Stabilimento di Garbagnate
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Olon S.p.A.
Sede Legale
Strada Rivoltana km 6/7
Rodano (MI)



Certificate of analysis

Product **MINOXIDIL-USP/EP current edition**

Code N° **2610290**

Batch N° **1610001416**

Manufacturing date **JUL 2016**

Retest date (where applicable)

JUN 2021

Analysis Number **Q1PF070402**

Bulletin **4P1642800**

Test	References	Result	M.U.	Limits
Description		White crystalline powder		White to off-white crystalline powder
IR		Conforms to standard		Conforms to standard
UV and VISIBLE absorption		Conforms		Conforms
Loss on drying		0,1	%	≤ 0,5
Residue on ignition		0,1	% db	≤ 0,1
Heavy metals		< 20	ppm	≤ 20
Appearance of solution		Not more coloured than Y6		Not more coloured than Y6
Appearance of solution		Clear	--	Clear
Assay (HClO ₄)		99,7	%	99,0 + 101,0
HPLC: Assay		97,6	%	97,0 + 103,0
		< 0,05	%	≤ 0,15
2,4-Diamino-6-ChloroPyrimidine (Impurity B)		< 0,05	%	≤ 0,2
2,4-Diamino-6-Piperidinpyrimidine (Impurity E or deoxyminoxidil)				
Largest unknown impurity		< 0,05	%	≤ 0,10
Total impurities by EP		< 0,05	%	≤ 0,3
Total impurities by USP		< 0,05	%	≤ 0,3
OVI (USP): Not used		Not tested		Not tested
ICH Class 1 solvents : Not used		Not tested	--	Not tested
ICH Class 2 solvents : Not used		Not tested	--	Not tested
ICH Class 3 solvents		Conforms	--	Conforms
2-Propanol		486	ppm	≤ 2000
Acetone		148	ppm	≤ 1000
Packaging and storage		Preserve well-closed container	--	Preserve well-closed container

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. e P. IVA n. 08101100157 - R.E.A. Milano n. 1201640

Società del Gruppo P & R S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Strada Rivoltana km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00651030181

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Analysis Date

08/29/2016

QC Manager

29 AGO, 2016

Reviewed by Qualified Person

Notes:

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A).
Manufacturing site of the Active Pharmaceutical Ingredient: Stabilimento di Garbagnate