

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° **1410000150**

Manufacturing date **APR 14** Retest date (where applicable) **APR 2019**

Analysis Number **Q4PF041702** Bulletin **4P1462166**

Test	References	Result	M.U.	Limits
Description		White crystalline powder	--	White to off-white crystalline powder
IR		Complies to standard	% db	Complies to standard
UV and VISIBLE absorption		Complies	--	Complies
Weight loss		0,1	%	≤ 0,5
Sulphated Ash		0,1	%	≤ 0,1
Heavy metals		< 20	ppm	≤ 20
Appearance of solution		Not more coloured than Y6	% db	Not more coloured than Y6
Appearance of solution		Clear	--	Clear
Assay (HClO4)		99,3	% db	99,0 + 101,0
HPLC: Assay		100,0	%	97,0 + 103,0
		< 0,05	dried % db	≤ 0,15
2,4-Diamino-6-ChloroPyrimidine (Impurity B)	< 0,01 (LOQ)	< 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	% db	≤ 0,3
Total impurities by USP		0,1	% db	≤ 0,3
OVI (USP): Not used		Not tested	% db	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		Complies	--	Complies
2-Propanol		532	ppm	≤ 2000
Acetone		36	ppm	≤ 1000
Packaging and storage		Preserve well-closed container	--	Preserve well-closed container

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fis. a 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 - 20080 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00651030181

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Analysis Date

05/06/2014

QC Manager

05 MAG. 2014

Reviewed by Qualified Person

[Signature]

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