

Stabilimento di Garbagnate Milanese
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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° **1340846**

Manufacturing date **Dec 2013** Retesting date (where applicable) **Nov 2018** Expiration date (where applicable) **Nov 2018**

Analysis Number		N4PF120202		
Test	References	Results	M.U.	Limits
Appearance		White, crystalline powder	--	White to off-white crystalline powder
Identification				
- IR		Conforms to Standard	--	Conforms to Standard
- UV		Conforms	--	Conforms
Loss on drying		0,1	%	≤ 0,5
Residue on ignition		0,1	%	≤ 0,1
Heavy metals		≤ 20	ppm	≤ 20
Appearance of solution		Not more coloured than Y-8	--	Not more coloured than Y-8
Assay				
- Assay (perchloric acid)		99,2	% dried	98,5 + 101,0
- Assay (HPLC)		99,2	% dried	97,0 + 103,0
Related substances				
- 2,4-Diamino-6-ChloroPyrimidine (Impurity B)		≤ 0,05	%	≤ 0,2
- 2,4-Diamino-6-ChloroPyrimidine-3-Oxide (Impurity A)	≤ 0,01 (LOQ)	≤ 0,05	%	≤ 0,2
- 2,4-Diamino-6-Piperidinpyrimidine (Impurity E or deoxyminoxidil)	≤ 0,01 (LOQ)	≤ 0,05	%	≤ 0,2
- Largest unknown impurity		≤ 0,05	%	≤ 0,10
- Total impurities		≤ 0,05	%	≤ 1,5
Residual solvents (GC)				
- 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		1164	ppm	≤ 2000
- Acetone <12 (LOQ)		147	ppm	≤ 1000
Packaging and storage		Preserve well-closed container	--	Preserve well-closed container

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: OLON S.p.A. - Garbagnate

Date

03/01/2014

CQ Manager (Roberto Quaglia)

03/GEN. 2014

Reviewed by Qualified Person

[Signature] 03/01/14

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 F. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo F. & R. S.p.A.
Strada Rivoltana km 6/7 - 20060 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. n. P.I. 00991030151