

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° **1340551**

Manufacturing date **Jul 2013**

Retesting date
(where applicable)

Jun 2018

Expiration date
(where applicable)

Analysis Number N4PF070801		Limits		
Test	Results	M.U.	Min	Max
Description	White, crystalline powder		White, crystalline powder	Off-white
Identification				
- IR	Conforms to Standard		Conforms to Standard	
- UV	Conforms		Conforms	
Loss on drying	0,1	%		0,5
Residue on Ignition	0,0	%		0,1
Heavy metals	< 20	ppm		20
Appearance of Solution	Not more coloured than Y-6		Not more coloured than Y-6	
Assay (perchloric acid) :	98,5	%dried	98,5	101,0
Assay HPLC :	99,2	%dried	97,0	103,0
Related Substances HPLC :				
- 2,4-Diamino-6-Chloro-Pyrimidine	< 0,05	%		0,2
- 2,4-Diamino-6-Chloro-Pyrimidine-3-Oxide	< 0,05	%		0,2
- 2,4-Diamino-6-Piperidinopyrimidine	< 0,05	%		0,2
- Largest unknown Impurity	< 0,05	%		0,10
- Total Impurities	0,1	%		1,5
OVI (USP) : Not used			Not tested	
Residual Solvents (GC) :				
- ICH Class 1 Solvents: Not used			Not tested	
- ICH Class1 Solvents : Not used			Not tested	
- ICH Class 3 Solvents:				
-2-propanol	506	ppm	< 24 (LOQ)	2000
- Acetone	< 12	ppm	< 12 (LOQ)	1000
Packaging and Storage		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 MIL.

Date

July 18, 2013

Q.C. Manager (Roberto Quaglia)

Reviewed by Qualified Person