Lote: 907/113

Stabilimento di Garbagnate Milanese
Via Milano, 166
20024 Garbagnate Milanese (MI)

PEC. olon@pec.olonspa.it
Telefono 02.99442.1
Fax 02.99442.220

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

olon s.p.a.

CERTIFICATE OF ANALYSIS

Product MINOXIDIL-USP/EP current edition **Code N°** 2610290 **Batch N°** 1340552

Manufacturing date Jul 2013 **Retesting date (where applicable)** Jun 2018 **Expiration date (where applicable)**

Analysis Number	N4PF070901		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) :	98,8	%dried	98,5	101,0
Assay HPLC :	99,1	%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-Piperidinpyrimidine	< 0,05	%		0,2
- Largest unknown Impurity	< 0,05	%		0,10
- Total Impurities	0,4	%		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	453	ppm	< 24 (LOQ)	2000
- Acetone	13	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.se

Date

July 18 ,2013

Q.C. Manager (Roberto Quaglia)

Reviewed by Qualified Person