



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		
Test	Results	M.U.	Limits	
			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-8-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.aa

Date

July 18, 2013

R.C. Manager (Roberto Quaglia)

Reviewed by Qualified Person.