

Stabilimento di Gerbagnate Milanese
Via Milano, 186
20024 Gerbagnate Milanese (MI)

PEC: olon@pec.olonspa.it
Telefono 0362.8250.1
Fax 0362.812008

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°

1340847

Manufacturing date

Dec 2013

Retesting date
(where applicable)

Nov 2018

Expiration date
(where applicable)

Nov 2018

Analyse Number		N4PF120401			
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-6	--	Not more coloured than Y-6	
Assay					
- Assay (perchloric acid)		100.4	% dried	98.5 + 101.0	
- Assay (HPLC)		98.5	% 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-Piperidinopyrimidine (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)					
- OV (I:BP): 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		678	ppm	≤ 2000	
- Acetone ≤ 12 (LOQ)		38	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. - Gerbagnate

Date

03/01/2014

CC Manager (Roberto Quaglia)

03 GEN. 2014

Reviewed by Qualified Person

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. - società all'attività di direzione e coordinamento della Società Cepogruppo P. & R. S.p.A.
Strada Rivoltana km 6/7 - 20060 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00851030161