Lote : 0020713

Stabilimento di Garbagnate
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Sede Legale
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olon s.p.a.

Certificate of analysis

Product MINOXIDIL-USP/EP current edition **Code N°** 2610290 **Batch N°** 1510000988

Manufacturing date MAY 2015 **Retest date (where applicable)** APR 2020

Analysis Number P1PF052002 **Bulletin** 4P1542525

Test	References	Result	M.U.	Limits
Description		Off-white crystalline powder		White to off-white crystalline powder
IR		Conforms to standard		Conforms to standard
UV and VISIBLE absorption		Conforms		Conforms
Loss on drying		0,1	%	≤ 0,5
Residue on ignition		0,1	% db	≤ 0,1
Heavy metals		< 20	ppm	≤ 20
Appearance of solution		Not more coloured than Y6		Not more coloured than Y6
Appearance of solution		Clear	--	Clear
Assay (HCLO4)		99,6	% dried	99,0 ÷ 101,0
HPLC: Assay		98,6	% dried	97,0 ÷ 103,0
2,4-Diamino-6-ChloroPyrimidine (Impurity B)		< 0,05	%	≤ 0,15
2,4-Diamino-6-Piperidinpyirimidine (Impurity E or deoxyminoxidil)		< 0,05	%	≤ 0,2
Largest unknown impurity		< 0,05	%	≤ 0,10
Total impurities by EP		< 0,05	%	≤ 0,3
Total impurities by USP		< 0,05	%	≤ 0,3
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		425	ppm	≤ 2000
Acetone		159	ppm	≤ 1000
Packaging and storage		Preserve well-closed container	--	Preserve well-closed container

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Test	References	Result	M.U.	Limits

Analysis Date

06/29/2015

QC Manager

29 GIU. 2015

Reviewed by Qualified Person

Notes:
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: Stabilimento di Garbagnate