

Stabilimento di Mulazzano
Via della vittoria, 89
Mulazzano

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



Certificate of analysis

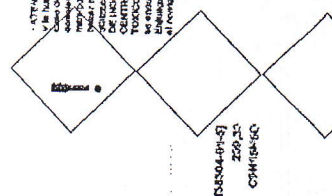
Product **MINOXIDIL EP/USP (CURRENT EDITIONS)** ✓ Code N° **17150** ✓ Batch N° **1520002654** ✓

Manufacturing date **OCT 2015** Retest date (where applicable) **AUG 2020** ✓

Analysis Number **P1PF102601** Bulletin **1P1585394**

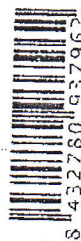
Test	References	Result	M.U.	Limits
Packaging and storage		Store in tightly closed containers	—	Store in tightly closed containers
Description		White crystalline powder	--	White to off-white crystalline powder
IR	EP (2.2.24) USP <197M>	Conform to standard	--	Conform to standard
UV		Complies	--	Complies
Loss on drying		0,1	%	≤ 0,5
Sulphated Ash	EP (2.4.14) USP <281>	< 0,05	%	≤ 0,1
Heavy metals	EP (2.4.8) Method H I USP <231> Method II	<20	ppm	≤20
Appearance of solution	EP (2.2.1) and (2.2.2)	Clear, not more coloured than Y6	--	Clear, not more coloured than Y6
2,4-Diamino-6-ChloroPyrimidine (Impurity B)	EP (2.2.29)	<0,05	%	≤ 0,15
2,4-Diamino-6-Piperidinopyrimidine (Impurity E or deoxyminoxidil)	EP (2.2.29)	<0,05	%	≤ 0,2
Each unknown impurity	EP (2.2.29)	<0,05	%	≤ 0,10
Total Impurities	EP (2.2.29)	<0,05	%	≤ 0,3
Total Impurities	USP <621>	<0,05	%	≤ 0,3
Assay (HPLC)	USP	99,3	%	97,0 - 103,0
Assay (HClO4)	EP (2.2.20)	100,6	%	99,0 - 101,0
Isopropyl alcohol		36	ppm	≤ 2000
Acetone		10	ppm	≤ 1000
Particle size	Internal method	For Information		For Information

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MINOXIDIL GRANEL

09-12-2015 83786



Lote: 0052706



QC-00166499

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. e P. IVA n. 08101100157 - R.E.A. Milano n. 1201040
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Strada Rivollana km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00651030181

Certificate of analysis

Product **MINOXIDIL EP/USP (CURRENT EDITIONS)** Code N° **17150** Batch N° **1520002654**

Manufacturing date **OCT 2015** Retest date (where applicable) **AUG 2020**

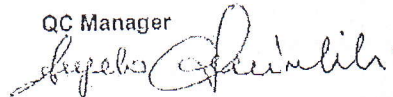
Analysis Number **P1PF102601** Bulletin **1P1585394**

Test	References	Result	M.U.	Limits

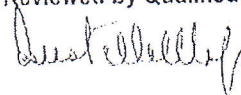
Analysis Date

11/27/2015

QC Manager



Reviewed by Qualified Person



Notes:

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7)
Manufacturing site of the Active Pharmaceutical Ingredient: Stabilimento di Mulazzano



MASTERSIZER

2000

Result Analysis Report

Sample Name:
Minoxidil - Average
Sample Source & type:
Factory = Mulazzano
Sample bulk lot ref:
17150 1520002654

SOP Name:
Minoxidil
Measured by:
righini
Result Source:
Averaged

Measured:
giovedì 26 novembre 2015 8.56.58
Analysed:
giovedì 26 novembre 2015 8.56.59

Particle Name:
Fraunhofer
Particle RI:
0.000
Dispersant Name:
esano

Accessory Name:
Hydro 2000MU (A)
Absorption:
0
Dispersant RI:
1.000

Analysis model:
General purpose
Size range:
0.020 to 2000.000 μm
Weighted Residual:
0.471 %

Sensitivity:
Enhanced
Obscuration:
14.80 %
Result Emulation:
Off

Concentration:
0.0531 %Vol

Span :
1.664
Surface Weighted Mean D[3,2]:
23.347 μm

Uniformity:
0.514
Vol. Weighted Mean D[4,3]:
66.201 μm

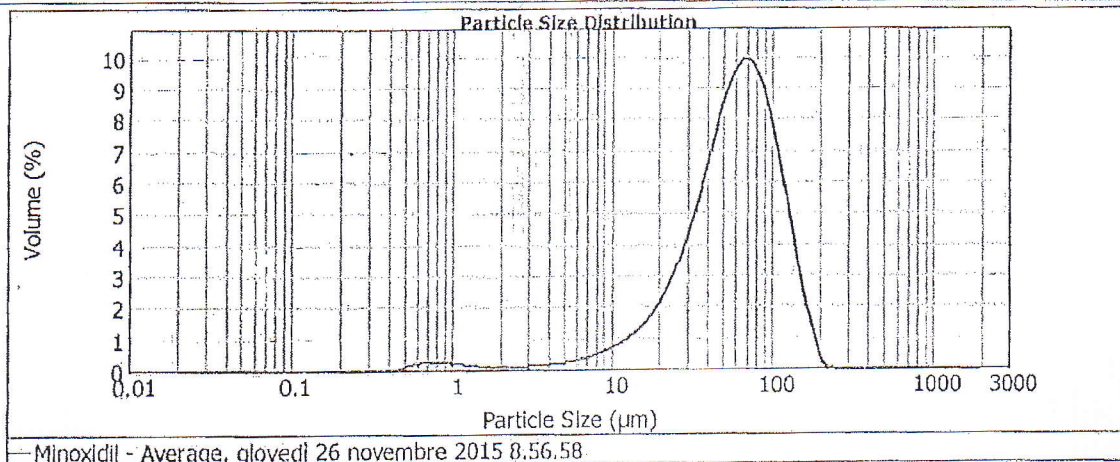
Result units:
Volume

Specific Surface Area:
0.257 m^2/g

d(0.1): 20.393 μm

d(0.5): 60.184 μm

d(0.9): 120.565 μm



Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.126	0.00	0.693	0.01	6.637	2.48	17.000	7.82	33.005	27.01	200.000	99.60
0.142	0.00	1.002	0.00	6.325	2.69	17.300	8.00	41.774	33.10	224.404	99.80
0.169	0.00	1.125	1.13	7.096	2.95	17.400	8.09	60.238	39.23	251.785	100.00
0.178	0.00	1.262	1.26	7.032	3.27	17.825	8.32	66.368	45.85	282.600	100.00
0.200	0.00	1.418	1.35	8.634	3.66	18.000	8.43	83.243	53.14	316.979	100.00
0.224	0.00	1.689	1.43	9.300	3.82	19.000	9.07	70.953	60.59	366.666	100.00
0.252	0.00	1.763	1.49	9.600	3.90	19.200	9.20	75.000	64.16	400.000	100.00
0.283	0.00	2.000	1.65	10.024	4.13	19.300	9.27	79.621	67.99	447.744	100.00
0.317	0.00	2.244	1.60	11.247	4.70	19.400	9.33	89.337	78.09	502.377	100.00
0.358	0.00	2.518	1.67	12.619	5.39	20.000	9.73	99.990	81.39	603.677	100.00
0.399	0.00	2.825	1.74	14.169	6.19	21.000	10.42	100.237	81.82	632.456	100.00
0.448	0.00	3.170	1.82	14.200	6.21	22.440	11.45	112.468	87.12	709.027	100.00
0.602	0.02	3.657	1.82	14.300	6.27	25.000	13.43	128.191	91.68	786.214	100.00
0.684	0.11	3.991	2.03	14.400	6.32	25.179	13.67	141.568	95.16	800.000	100.00
0.632	0.25	4.477	2.15	14.600	6.39	28.251	16.17	168.003	97.58	833.357	100.00
0.710	0.43	5.000	2.30	15.000	6.66	31.600	19.36	170.260	98.00		
0.786	0.62	5.024	2.30	15.837	7.16	36.666	23.22	180.000	99.17		

Operator notes:

26-11-15

26-11-15R

Malvern Instruments Ltd.
Malvern, UK
Tel : +[44] (0) 1684-892456 Fax +[44] (0) 1684-892769

MasterSizer 2000 Ver. 5.60
Serial Number : 34355-66

File name: 17150
Record Number: 494
26/11/2015 8.58.24