

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



Product	MINOXIDIL EP/USP (CURRENT EDITIONS) ✓	Code No	17150 ✓	Batch No	1520000653 ✓
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JAN 2020

1P1503874

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	%	≤ 0,6
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-Piperidinpyrimidine (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>	<0,01	%	≤ 0,3
Assay (HPLC)	USP	99,4	%	97,0 - 103,0
Assay (HClO4)	EP (2.2.20)	99,7	%	99,0 - 101,0
Isopropyl alcohol		63	ppm	≤ 2000
Acetone		29	ppm	≤ 1000
Particle size	Internal method	For information		For information

- ATENCION: Proveedor del FCM y la farmacia debe verificar el origen de la sustancia y la pureza de la misma antes de utilizarla. Se debe verificar el origen de la sustancia y la pureza de la misma antes de utilizarla. Se debe verificar el origen de la sustancia y la pureza de la misma antes de utilizarla.

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MINOXIDIL GRANEL

937962

[illegible][illegible]

LEVEL

GRAND

OXIDIZING

Mining
 • **Minerals**
 • **Metals**
 • **Nonferrous**
 • **Other**

7962

004591

30-03
13278
Lote:

Capitale Sociale € 40.000.000 IV. - R.L. Milano, Cor. Belgio, 6 P. IVA n. 00101100167 - R.E.A. Milano n. 1201040
Sedi del Gruppo P. & R. S.p.A. soggetta all'Istituto di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Sede Direzione IVA n. 0202910045 (R) - ITALY capitale sociale € 12.000.000,00 IV. - C.F. e P.I. 04651030181

30-03-2015

MINOXIDIL GRANEL

ota-0045989

QC-00158052

Revision

Certificate of analysis

Product MINOXIDIL EP/USP (CURRENT EDITIONS) Code N° 17150 Batch N° 1520000653

Manufacturing date MAR 2015 Retest date (where applicable) JAN 2020

Analysis Number P1PF031201 Bulletin 1P1583874

Test	References	Result	M.U.	Limits
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Analysis Date

03/24/2015

QC Manager

[Signature]

Reviewed by Qualified Person

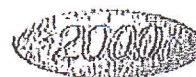
[Signature]

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 Muzzano



MASTERSIZER



Result Analysis Report

Sample Name:
Minoxidil - Average
Sample Source & type:
Factory = Mulazzano
Sample bulk lot ref:
17160-1520000653

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

Measured:
16 March 2015 12:17:44
Analysed:
16 March 2015 12:17:45

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:
0.374 %

Sensitivity:
Enhanced
Obscuration:
13.52 %
Result Emulation:
Off

Concentration:
0.0371 %Vol

Span:
1.908

Uniformity:
0.586

Result units:
Volume

Specific Surface Area:
0.334 m^2/g

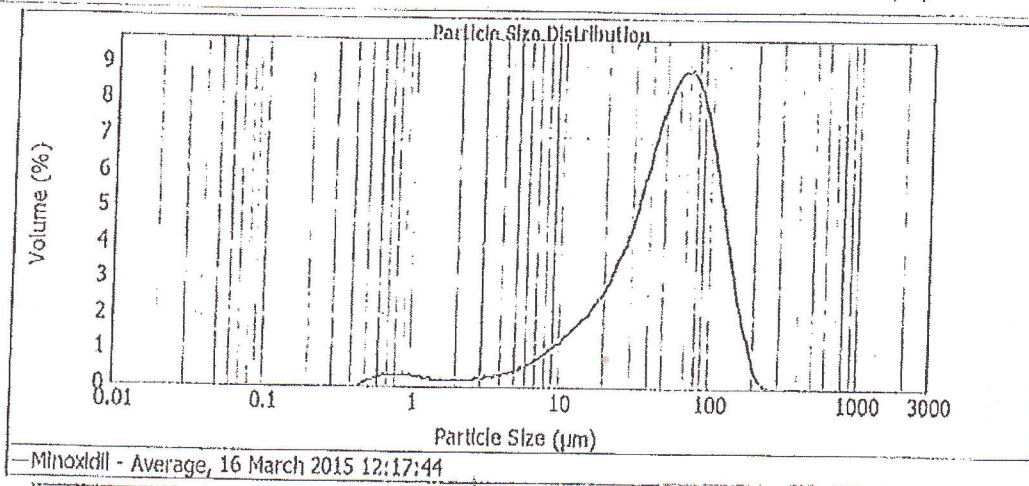
Surface Weighted Mean D[3,2]:
17.990 μm

Vol. Weighted Mean D[4,3]:
61.935 μm

d(0.1): 13.409 μm

d(0.5): 55.361 μm

d(0.9): 119.104 μm



Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.020	0.00	0.375	0.00	2.625	2.00	15.000	11.27	70.000	64.09
0.025	0.00	0.448	0.00	3.170	2.77	16.691	12.01	78.821	70.60
0.031	0.00	0.502	0.00	3.657	2.93	17.625	13.63	83.337	70.60
0.039	0.00	0.561	0.14	3.991	3.17	18.600	13.78	89.930	82.65
0.049	0.00	0.632	0.32	4.477	3.43	19.000	14.62	100.237	82.77
0.060	0.00	0.710	0.66	5.024	3.73	20.000	15.48	112.400	87.82
0.073	0.00	0.795	0.80	5.637	4.00	21.000	16.33	126.181	91.91
0.088	0.00	0.890	1.06	6.325	4.62	22.440	17.68	141.669	95.19
0.105	0.00	1.000	1.30	7.066	5.00	25.170	20.01	160.000	97.45
0.125	0.00	1.125	1.51	7.892	5.04	28.251	22.03	178.250	98.03
0.148	0.00	1.262	1.70	8.934	5.36	31.698	25.11	200.000	99.73
0.174	0.00	1.415	1.85	10.000	5.61	35.676	29.03	224.494	99.16
0.203	0.00	1.580	1.99	11.024	5.79	39.605	34.37	261.785	100.00
0.235	0.00	1.763	2.10	12.247	6.18	44.774	39.32	292.000	100.00
0.271	0.00	2.000	2.22	13.610	6.51	50.233	44.00	315.019	100.00
0.311	0.00	2.244	2.31	14.150	10.97	53.255	57.44	356.662	100.00
0.356	0.00	2.618	2.45						

Operator notes:

16-3-15R
16-1516