

Olon Spa Stab. Mulazzano
Via della Vittoria 89
26837 Mulazzano (LO)

PEC: olona.pec@olonspa.it
Tel. HQ: +39 02 9523.1
Tel. Plant: +39 02 9888921

Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
Rodano (MI)



Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 1920000777
Order 1190441
Quantity 275,000

Manufacturing date 06/04/2019
Re-test date 24/03/2024
Certificate Nr. 100000002853
Batch Size 974,000
Ref. Order PO 2019 - 1/ 47

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
Appearance	EP	White or almost white crystalline powder		White crystalline powder
Identification (IR)	EP (2.2.24)/USP <197	IR spectrum conforms to standard		Complies
Loss on drying	EP 2.2.32	<=0,5	%	0,13
Residue on ignition	EP 2.4.14 USP < 281	<=0,1	%	0,01
Heavy Metals	EP (2.4.8) Method H/ USP # Method II	<=20 ppm		<20 ppm
Appearance of solution Y6	EP(2.2.1)/(2.2.2)	Clear and not more coloured than Y6		Clear and not more coloured than Y6
Related substances (HPLC): 2,4-Diamine-6-ChloroPyrimidine (impurity B)	EP 2.2.29	<= 0,15	%	< 0,05
Related substances (HPLC): 2,4-Diamine-6-Piperidinpyrimidine (impurity E or deoxyminoxidil)	EP 2.2.29	<=0,2	%	< 0,05
Related substances (HPLC): unspecified impurities	EP 2.2.29	<= 0,10	%	< 0,05
Related substances (HPLC): total impurities by EP	EP 2.2.29	<=0,3	%	< 0,05
Organic impurities: total impurities by USP	USP	<=0,3	%	< 0,05
Assay (HPLC) (on the anhydrous basis)	USP	97,0 - 103,0	%	99,5
Potentiometric assay (HClO4)	EP (2.2.20)	99,0 - 101,0	%	99,4
Residual solvents (GC): acetone	Internal Method	<= 1000	ppm	< LOQ (50)
Residual solvents (GC): Isopropyl Alcohol	Internal Method	<= 2000	ppm	< LOQ (100)
Particle size	Internal Method	On customer request		On customer request

This batch was manufactured, packaged and tested in compliance with ICH Q7 and EU GMP Guideline Volume 4 Part II.

Angelo Cavicchioli
QC Manager
Approved April 29, 2019

Laura Berra
Qualified Person
Released April 30, 2019

Emission April 30, 2019

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - R.E.A. Milano n. 1201640
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società capogruppo P. & R. S.p.A.
Strada Rivoltana Km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00651030181

Olon Spa Stab. Mulazzano
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26037 Mulazzano (LO)

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Manufacturing site of the Active Pharmaceutical Ingredient: Olon spa Mulazzano Plant.

Not to be used in sterile parenteral and sterile non-parenteral products.

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Result Analysis Report

Sample Name:
Minoxidil - Average

Sample Source & type:
Factory = Mulazzano

Sample bulk lot ref:
17150 1920000777

SOP Name:
Minoxidil

Measured by:
righini

Result Source:
Averaged

Measured:
mercoledì 17 aprile 2019 11:18:59

Analysed:
mercoledì 17 aprile 2019 11:19:00

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:
0.755 %

Sensitivity:
Enhanced

Obscuration:
18.94 %

Result Emulation:
Off

Concentration:
0.0911 %Vol

Span :
2.003

Uniformity:
0.615

Result units:
Volume

Specific Surface Area:
0.196 m^2/g

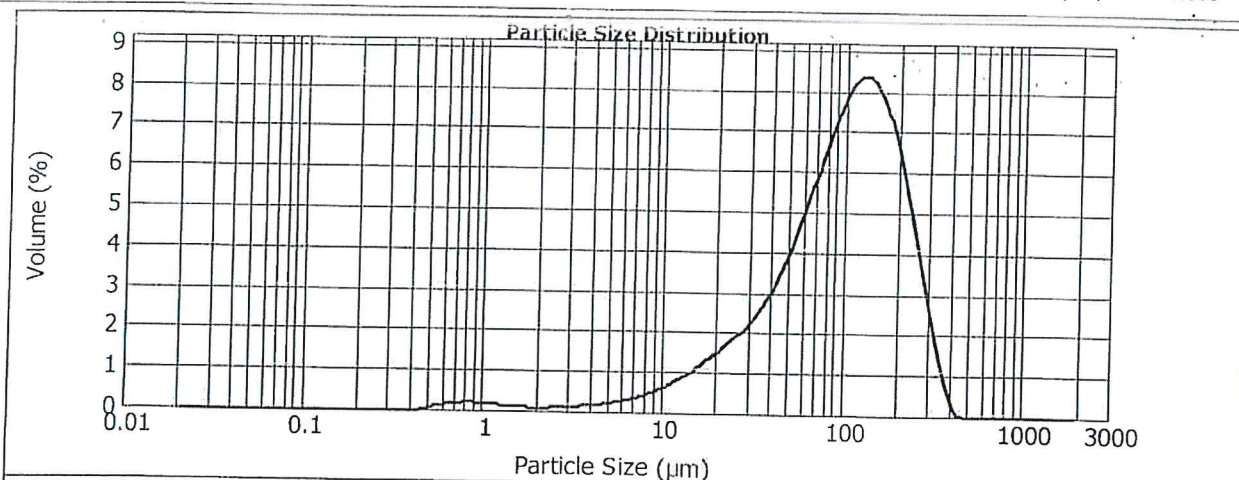
Surface Weighted Mean D[3,2]:
30.557 μm

Vol. Weighted Mean D[4,3]:
116.450 μm

d(0.1): 24.043 μm

d(0.5): 102.232 μm

d(0.9): 228.838 μm



— Minoxidil - Average, mercoledì 17 aprile 2019 11:18:59

Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.200	0.00	1.416	1.03	7.096	2.61	17.300	6.81	44.774	19.93	224.404	88.29
0.224	0.00	1.589	1.11	7.962	2.99	17.400	6.86	50.238	22.66	250.000	92.86
0.252	0.00	1.783	1.19	8.934	3.23	17.825	7.06	56.368	25.82	251.785	93.08
0.283	0.00	2.000	1.25	9.300	3.36	18.000	7.14	63.246	29.43	282.508	95.98
0.317	0.00	2.244	1.32	9.500	3.44	19.000	7.61	70.953	33.56	316.979	98.03
0.356	0.00	2.518	1.39	10.000	3.63	19.200	7.70	75.000	35.73	355.656	99.28
0.399	0.00	2.825	1.46	10.024	3.64	19.300	7.75	79.621	38.21	399.052	99.88
0.448	0.00	3.170	1.54	11.247	4.12	19.400	7.80	89.337	43.37	400.000	99.88
0.502	0.01	3.557	1.64	12.619	4.69	20.000	8.08	99.990	48.87	447.744	100.00
0.564	0.07	3.991	1.75	14.159	5.37	21.000	8.55	100.237	49.00	502.377	100.00
0.632	0.17	4.477	1.87	14.200	5.39	22.440	9.24	112.468	54.99	563.677	100.00
0.710	0.30	5.000	2.01	14.300	5.43	25.000	10.45	126.191	61.20	632.456	100.00
0.796	0.43	5.024	2.02	14.400	5.48	25.179	10.54	141.589	67.48	709.627	100.00
0.893	0.57	5.637	2.18	14.500	5.52	28.251	11.99	158.866	73.61	796.214	100.00
1.002	0.71	6.000	2.29	15.000	5.75	31.698	13.62	176.250	79.42	800.000	100.00
1.125	0.83	6.325	2.38	15.887	6.15	35.566	15.46	180.000	79.89	893.367	100.00
1.262	0.94	6.400	2.40	17.000	6.67	39.905	17.55	200.000	84.70		

Operator notes:

17/04/19

17150-2359