

Stabilimento di Molazzano
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Molazzano

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



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

Certificate of analysis

Product **MINOXIDIL EP/USP (CURRENT EDITIONS)** Code N° **17150** Batch N° **1720001434**

Manufacturing date **JUN 2017** Retest date (where applicable) **APR 2022**

Analysis Number **R1PF060802** Bulletin **1P1789689**

Test	References	Result	M.U.	Limits
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		0,12	%	≤ 0,5
Sulphated Ash	EP (2.4.14) USP <281>	0,02	%	≤ 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>	<0,05	%	≤ 0,3
Assay (HPLC)	USP	99,1	%	97,0 103,0
Assay (HClO4)	EP (2.2.20)	100,2	%	99,0 101,0
Isopropyl alcohol		<100	ppm	≤ 2000
Acetone		<50	ppm	≤ 1000
Particle size	Internal method	For information		For information

Result Analysis Report

Sample Name:
Minoxidil - Average

Sample Source & type:
Factory = Mulazzano

Sample bulk lot ref:
17150 1720001434

SOP Name:
Minoxidil

Measured by:
faccenda

Result Source:
Averaged

Measured:
giovedì 22 giugno 2017 15.05.59

Analysed:
giovedì 22 giugno 2017 15.06.00

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 μ m

Weighted Residual:
0.485 %

Sensitivity:
Enhanced

Obscuration:
13.26 %

Result Emulation:
Off

Concentration:
0.0893 %Vol

Span :
1.726

Uniformity:
0.529

Result units:
Volume

Specific Surface Area:
0.309 m^2/g

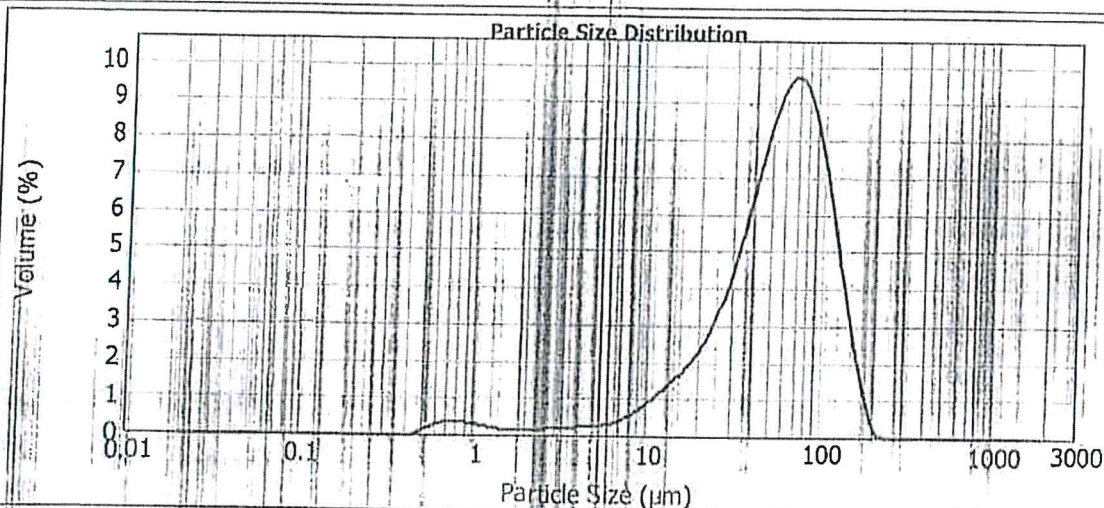
Surface Weighted Mean D[3,2]:
19.438 μ m

Vol. Weighted Mean D[4,3]:
63.953 μ m

d(0.1): 17.374 μ m

d(0.5): 58.297 μ m

d(0.9): 118.003 μ m



Minoxidil - Average, giovedì 22 giugno 2017 15.05.59

Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.178	0.00	1.282	1.70	6.400	3.67	17.000	9.74	39.005	30.08	200.000	99.90
0.200	0.00	1.416	1.84	7.093	3.91	17.300	9.95	44.774	35.36	224.404	100.00
0.224	0.00	1.589	1.94	7.962	4.25	17.400	10.02	50.238	41.36	251.785	100.00
0.252	0.00	1.783	2.03	8.934	4.69	17.825	10.32	56.368	47.97	282.509	100.00
0.283	0.00	2.000	2.13	9.930	4.87	18.000	10.44	63.246	56.04	316.979	100.00
0.317	0.00	2.244	2.22	9.900	4.87	19.000	11.16	70.953	62.33	355.636	100.00
0.350	0.00	2.518	2.34	10.000	5.24	19.200	11.30	75.000	65.64	389.052	100.00
0.399	0.00	2.825	2.40	10.024	5.25	19.300	11.37	79.621	69.57	400.000	100.00
0.448	0.00	3.170	2.60	11.247	5.95	19.400	11.44	89.337	76.45	447.744	100.00
0.502	0.00	3.557	2.75	12.619	6.79	20.000	11.88	99.990	82.56	502.377	100.00
0.564	0.15	3.991	2.91	14.159	7.60	21.000	12.62	100.237	82.69	563.677	100.00
0.632	0.34	4.477	3.09	14.200	7.63	22.440	13.72	112.488	89.00	632.455	100.00
0.710	0.59	5.000	3.24	14.300	7.89	25.000	15.78	126.191	92.10	709.277	100.00
0.796	0.84	5.024	3.25	14.400	7.98	25.179	15.90	141.592	95.67	795.214	100.00
0.893	1.10	5.637	3.43	14.500	8.08	28.251	18.54	153.866	97.99	900.000	100.00
1.002	1.34	6.000	3.65	15.000	8.38	31.698	21.72	178.230	99.74	999.357	100.00
1.125	1.54	6.325	3.65	15.807	8.67	35.565	25.55	189.000	99.92		

Operator notes:

22.6.17
22.06.17