

Stabilimento di Mulazzano
Via della vittoria 39
Mulazzano

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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° **1720001433**

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

Analysis Number **R1PF060702** Bulletin **1P1789682**

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		0,17	%	≤ 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	97,7	%	97,0 - 103,0
Assay (HClO4)	EP (2.2.20)	100,7	%	99,0 - 101,0
Isopropyl alcohol		<100	ppm	≤ 2000
Acetone		<50	ppm	≤ 1000
Particle size	Internal method	For information		For information

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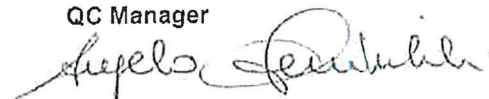
Analysis Number R1PF060702 Bulletin 1P1789682

Test	References	Result	M.U.	Limits

Analysis Date

06/26/2017

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

Result Analysis Report

Sample Name:
Minoxidil - Average

Sample Source & type:
Factory = Mulazzano

Sample bulk lot ref:
17150 1720001433

SOP Name:
Minoxidil

Measured by:
Iaccenda

Result Source:
Averaged

Measured:
giovedì 22 giugno 2017 14.54.17

Analysed:
giovedì 22 giugno 2017 14.54.18

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 um

Weighted Residual:
0.467 %

Sensitivity:
Enhanced

Obscuration:
11.62 %

Result Emulation:
Off

Concentration:
0.0471 %Vol

Span :
1.929

Uniformity:
0.597

Result units:
Volume

Specific Surface Area:
0.224 m²/g

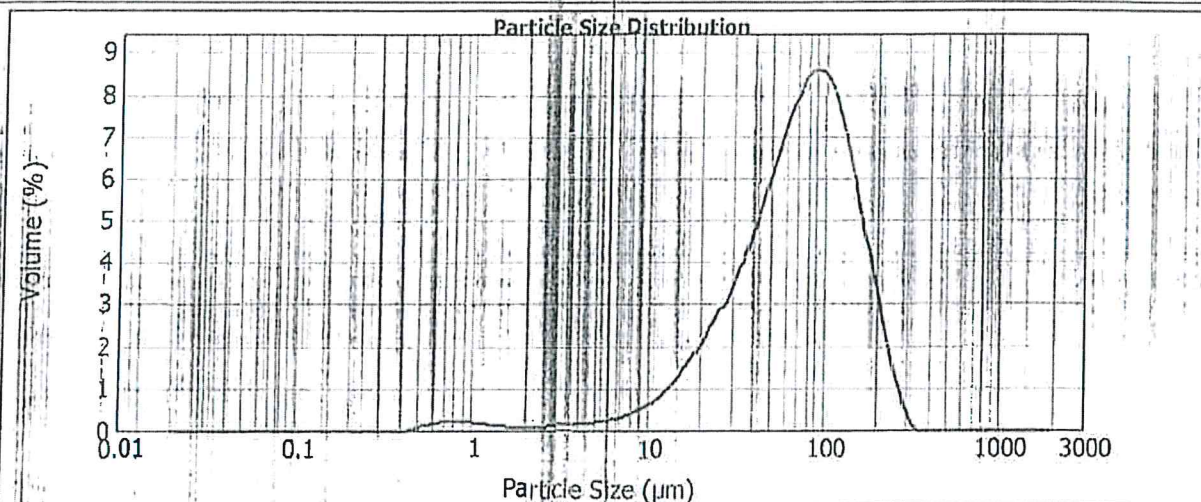
Surface Weighted Mean D[3,2]:
26.838 um

Vol. Weighted Mean D[4,3]:
85.738 um

d(0.1): 21.655 um

d(0.5): 74.728 um

d(0.9): 165.794 um



Minoxidil - Average, giovedì 22 giugno 2017 14.54.17

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	1.262	1.06	6.400	2.40	17.000	7.03	39.905	23.33	200.000	95.28
0.300	0.00	1.416	1.16	7.095	2.58	17.300	7.21	44.774	27.11	224.404	97.40
0.224	0.00	1.589	1.23	7.902	2.83	17.400	7.27	50.238	31.38	251.765	98.82
0.252	0.00	1.783	1.30	8.934	3.14	17.825	7.53	56.368	36.17	282.508	99.63
0.283	0.00	2.000	1.36	9.900	3.27	18.000	7.64	63.246	41.48	316.978	99.98
0.317	0.00	2.244	1.41	9.500	3.34	19.000	8.27	70.663	47.27	355.655	100.00
0.365	0.00	2.518	1.48	10.000	3.53	19.200	8.39	75.000	50.19	399.652	100.00
0.399	0.00	2.625	1.54	10.024	3.54	19.300	8.48	79.621	53.44	400.000	100.00
0.448	0.00	3.170	1.62	11.247	4.03	19.400	8.52	89.537	59.64	447.744	100.00
0.502	0.01	3.557	1.71	12.619	4.65	20.000	8.91	99.990	68.15	502.377	100.00
0.534	0.03	3.991	1.81	14.159	5.43	21.000	9.58	100.237	69.29	563.677	100.00
0.632	0.20	4.477	1.93	14.200	5.45	22.440	10.63	112.400	72.49	632.455	100.00
0.710	0.35	5.000	2.05	14.300	5.49	25.000	12.30	126.181	78.53	709.627	100.00
0.796	0.50	5.024	2.06	14.400	5.56	25.179	12.42	141.580	83.57	796.214	100.00
0.893	0.66	5.837	2.21	14.500	5.61	28.251	14.61	158.605	89.49	890.000	100.00
1.002	0.81	6.000	2.30	15.000	5.88	31.556	17.13	178.250	92.50	993.567	100.00
1.125	0.95	6.325	2.28	15.837	6.39	35.565	20.03	180.000	92.58		

Operator notes:

22-6-17
22.06.17