



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° **1820002004**

Manufacturing date **JUL 2018** Retest date (where applicable) **JUN 2023**

Analysis Number **S1PF072703** Bulletin **1P1893206**

Test	References	Result	M.U.	Limits
Description	EP	White crystalline powder	--	White or almost white crystalline powder
IR	EP (2.2.24) USP <197M>	Conforms to standard	--	Conforms to standard
Loss on drying	EP (2.2.32)	0,13	%	≤ 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-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	101,1	% dried	97,0 - 103,0
Assay (HClO4)	EP (2.2.20)	100,1	% dried	99,0 - 101,0
Isopropyl alcohol	Internal Method	< 100	ppm	≤ 2000
Acetone	Internal Method	< 50	ppm	≤ 1000
Particle size	Internal method	For information	--	For information

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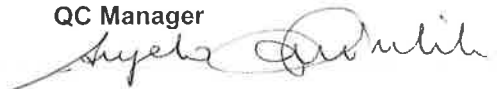
Analysis Number **S1PF072703** Bulletin **1P1893206**

Test	References	Result	M.U.	Limits

Analysis Date

09/15/2018

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 1820002004

SOP Name:
Minoxidil

Measured by:
righini

Result Source:
Averaged

Measured:
mercoledì 5 settembre 2018 8.40.25

Analysed:
mercoledì 5 settembre 2018 8.40.26

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:
0.631 %

Sensitivity:
Enhanced

Obscuration:
16.59 %

Result Emulation:
Off

Concentration:
0.0716 %Vol

Span :
1.518

Uniformity:
0.465

Result units:
Volume

Specific Surface Area:
0.216 m^2/g

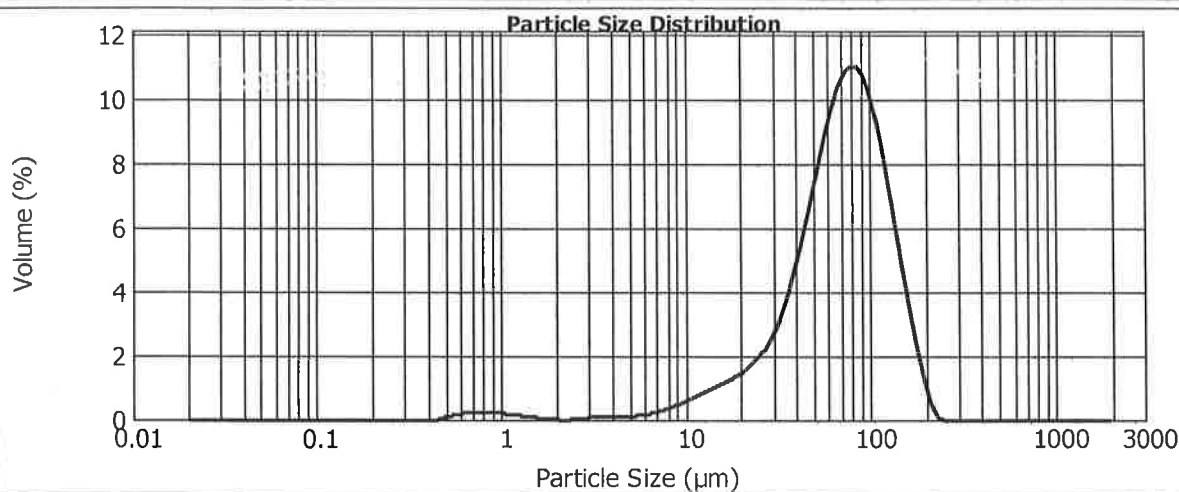
Surface Weighted Mean D[3,2]:
27.772 μm

Vol. Weighted Mean D[4,3]:
76.866 μm

d(0.1): 25.490 μm

d(0.5): 71.842 μm

d(0.9): 134.568 μm



—Minoxidil - Average, mercoledì 5 settembre 2018 8.40.25

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	1.22	7.096	2.02	17.300	6.11	44.774	23.38	224.404	99.96
0.224	0.00	1.589	1.28	7.962	2.23	17.400	6.16	50.238	28.43	250.000	100.00
0.252	0.00	1.783	1.31	8.934	2.52	17.825	6.36	56.368	34.47	251.785	100.00
0.283	0.00	2.000	1.31	9.300	2.64	18.000	6.44	63.246	41.43	282.508	100.00
0.317	0.00	2.244	1.31	9.500	2.71	19.000	6.90	70.963	49.14	316.979	100.00
0.356	0.00	2.518	1.31	10.000	2.89	19.200	6.99	75.000	53.03	355.656	100.00
0.399	0.00	2.825	1.34	10.024	2.90	19.300	7.04	79.621	57.32	399.052	100.00
0.448	0.00	3.170	1.39	11.247	3.38	19.400	7.09	89.337	65.59	400.000	100.00
0.502	0.02	3.557	1.45	12.619	3.97	20.000	7.36	99.990	73.39	447.744	100.00
0.564	0.10	3.991	1.51	14.159	4.66	21.000	7.83	100.237	73.56	502.377	100.00
0.632	0.23	4.477	1.58	14.200	4.68	22.440	8.51	112.468	80.82	563.677	100.00
0.710	0.39	5.000	1.65	14.300	4.73	25.000	9.75	126.191	87.05	632.456	100.00
0.796	0.57	5.024	1.65	14.400	4.77	25.179	9.84	141.589	92.04	709.627	100.00
0.893	0.74	5.637	1.74	14.500	4.82	28.251	11.46	158.866	95.71	796.214	100.00
1.002	0.90	6.000	1.80	15.000	5.05	31.698	13.47	178.250	98.14	800.000	100.00
1.125	1.03	6.325	1.86	15.887	5.46	35.566	16.02	180.000	98.29	893.367	100.00
1.262	1.14	6.400	1.87	17.000	5.97	39.905	19.28	200.000	99.49		

Operator notes:

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