

Lote: 9060717

Stabilimento di Mulazzano
Via della vittoria 89
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° **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

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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 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 mode:
General purpose

Size range:
0.020 to 2000.000 μm

Weighted Residual:
0.485 %

Sensitivity:
Enhanced

Obscuration:
13.26 %

Result Emulation:
Off

Concentration:
0.0393 %Vol

Specific Surface Area:
0.309 m^2/g

Span :
1.726

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

Uniformity:
0.529

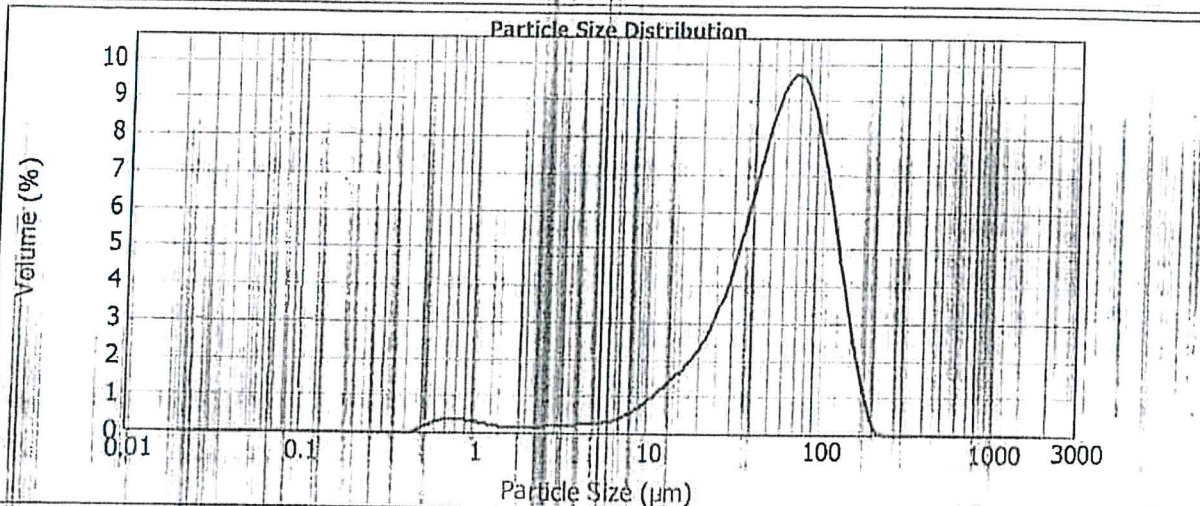
Vol. Weighted Mean D[4,3]:
63.953 μm

Result units:
Volume

d(0.1): 17.374 μm

d(0.5): 58.297 μm

d(0.9): 118.003 μm



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 %
0.176	0.00	1.262	1.70	6.400	3.67	17.000	9.74	39.905	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	7.932	4.25	17.400	10.02	50.238	41.36	251.785	100.00
0.252	0.00	1.763	2.03	8.834	4.69	17.825	10.32	56.368	47.97	282.503	100.00
0.283	0.00	2.000	2.13	9.300	4.87	18.000	10.44	63.246	55.04	316.979	100.00
0.317	0.00	2.244	2.22	9.500	4.97	18.200	11.16	70.993	62.33	355.656	100.00
0.350	0.00	2.518	2.34	10.000	5.24	18.400	11.30	75.000	65.64	399.002	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	18.400	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	99.960	82.56	502.377	100.00
0.564	0.15	3.991	2.91	14.159	7.70	21.000	12.67	100.237	82.69	563.677	100.00
0.632	0.34	4.477	3.08	14.200	7.83	22.440	13.72	112.488	88.00	632.456	100.00
0.710	0.59	5.000	3.24	14.300	7.89	25.000	15.76	126.191	92.10	709.277	100.00
0.796	0.84	5.024	3.25	14.400	7.98	25.179	15.90	141.509	95.67	796.214	100.00
0.893	1.10	5.637	3.43	14.500	8.06	28.251	18.54	153.866	97.99	893.357	100.00
1.002	1.34	6.000	3.55	15.000	8.36	31.698	21.72	178.250	99.74		
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