

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

PEC: olon@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 2020002316
Order 1202368
Quantity 25,000 KG

Manufacturing date 15/09/2020
Re-test date 31/08/2025
Certificate Nr. 100000012273
Batch Size 924,000 KG
Ref. Order 2020 6796

Test	References	Specification	M.U.	Result
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	M> EP 2.2.32	<=0,5	%	0,15
Residue on ignition	EP 2.4.14 USP < 281	<=0,1	%	0,03
Appearance of solution Y6	EP(2.2.1)(2.2.2)	Clear and not more coloured than Y6		Clear and not more coloured than
Related substances (HPLC): 2,4-diamine-6-chloropyrimidine (Impurity B) + 2,4-diamino-5,6-dichloropyrimidine-3-oxide	EP 2.2.29	<=0,10	%	< 0,00
Related substances (HPLC): 2,4-Diamine-6-Piperidinopyrimidine (Impurity E or deoxyminoxidil)	EP 2.2.29	<=0,2	%	< 0,01
Related substances (HPLC): unspecified impurities	EP 2.2.29	<= 0,10	%	0,02
Related substances (HPLC): total impurities by EP	EP 2.2.29	<=0,3	%	0,04
Organic impurities: total impurities by USP	USP	<=0,3	%	0,23
Assay (HPLC) (on dried basis)	USP	97,0 - 103,0	%	99,6
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	100,3
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

Angelo Cavicchioli QC Manager Approved October 12, 2020	Donatella Magani Qualified Person Released October 12, 2020
'Emission'	Donatella Magani Qualified Person October 20, 2020

Capitale Sociale € 40.000.000 I.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640

Società Capogruppo P. & R. Principi Attivi S.p.A.

Società con Socio unico - Strada Rivoltana Km. 6/7 - 20053 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v. - C.F. e P.IVA 11155530964

Modello: 17150-STD / 3

October 20, 2020

This CoA is electronically dated and signed by authorized personnel of the Quality Unit

October 20, 2020

Pag. 1 / 2

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

PEC: olon@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 2020002316
Order 1202368
Quantity 25,000 KG

Manufacturing date 15/09/2020
Re-test date 31/08/2025
Certificate Nr. 100000012273
Batch Size 924,000 KG
Ref. Order 2020 6796

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-------------	-------------------	----------------------	-------------	---------------

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

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

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

Angelo Cavicchioli QC Manager Approved October 12, 2020	Donatella Magani Qualified Person Released October 12, 2020
'Emission'	Donatella Magani Qualified Person October 20, 2020

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640
Società Capogruppo P. & R. Principi Attivi S.p.A.
Società con Socio unico - Strada Rivoltana km. 6/7 - 20053 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v. - C.F. e P.IVA 11155530964

Modello: 17150-STD / 3

October 20, 2020

This CoA is electronically dated and signed by authorized personnel of the Quality Unit October 20, 2020

Pag. 2 / 2

Particle size distribution

Measurement Details

Operator Name Righini
Sample Name Average of 'MINOXIDIL'
SOP File Name Minoxidil.msop
Code 17150
Batch 2020002316

Measurement Details

Analysis Date Time 16/09/2020 11:03:57
Measurement Date Time 16/09/2020 11:03:57
Result Source Averaged

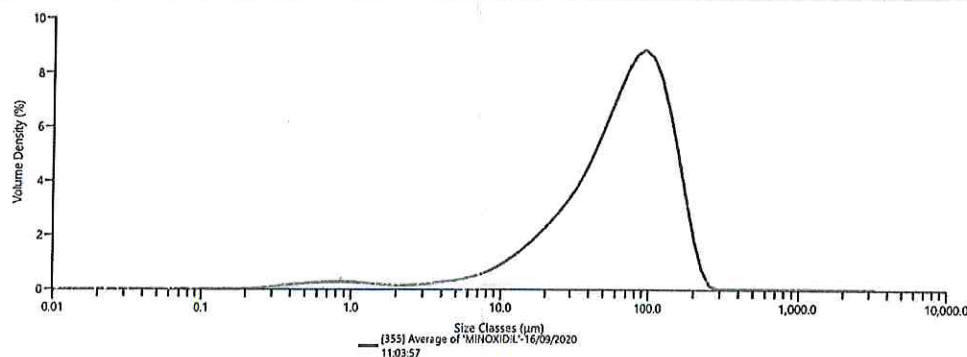
Analysis

Particle Name minoxidil
Particle Refractive Index 0.000
Particle Absorption Index 0.000
Dispersant Name Hexane
Dispersant Refractive Index 1.000
Scattering Model Fraunhofer
Analysis Model General Purpose
Weighted Residual 1.03 %
Laser Obscuration 13.49 %

Result

Concentration 0.0294 %
Span 1.886
Uniformity 0.584
Specific Surface Area 376.8 m²/kg
D [3,2] 15.167 µm
D [4,3] 73.809 µm
Dv [10] 15.130 µm
Dv [50] 67.307 µm
Dv [90] 142.053 µm
Volume In Range (0,5) µm 3.90 %
Volume In Range (0,20) µm 13.65 %

Frequency (compatible)



Result

Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under
0.010	0.00	0.077	0.00	0.594	0.87	4.583	3.71	35.335	25.21	272.433	100.00
0.011	0.00	0.080	0.00	0.675	1.00	5.207	3.99	40.146	28.87	309.525	100.00
0.013	0.00	0.100	0.00	0.767	1.29	5.916	4.31	45.613	33.07	351.670	100.00
0.015	0.00	0.113	0.00	0.872	1.53	6.722	4.70	51.823	37.32	399.555	100.00
0.017	0.00	0.128	0.00	0.991	1.74	7.637	5.16	58.880	43.45	453.500	100.00
0.019	0.00	0.146	0.00	1.125	1.95	8.677	5.72	66.837	49.67	515.772	100.00
0.022	0.00	0.166	0.00	1.279	2.14	9.956	6.41	76.024	55.51	584.001	100.00
0.024	0.00	0.188	0.00	1.453	2.31	11.201	7.25	86.355	63.77	665.793	100.00
0.026	0.00	0.214	0.00	1.651	2.45	12.726	8.27	98.114	71.19	756.449	100.00
0.032	0.00	0.243	0.00	1.875	2.58	14.458	9.49	111.473	76.39	819.450	100.00
0.035	0.00	0.276	0.04	2.131	2.71	16.427	10.83	126.652	84.59	976.475	100.00
0.041	0.00	0.311	0.12	2.423	2.83	18.664	12.61	143.887	93.56	1109.425	100.00
0.046	0.00	0.357	0.23	2.750	2.95	21.205	14.54	163.490	94.65	1260.499	100.00
0.053	0.00	0.405	0.33	3.125	3.10	24.012	16.39	185.732	97.74	1432.138	100.00
0.060	0.00	0.459	0.51	3.550	3.27	27.373	19.21	211.044	99.32	1627.136	100.00
0.068	0.00	0.523	0.68	4.014	3.47	31.100	22.02	239.790	99.93	1848.632	100.00

Particle size distribution

OLON S.p.A.



Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
355	Average of 'MINOXIDIL'	Unlocked	DESKTOP-2NCOHTJ\Righini	16/09/2020 11:05:39 +02:00
		Locked	DESKTOP-2NCOHTJ\Cersosimo	16/09/2020 11:14:13 +02:00

