

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)

101e 0060520



Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2020000499
Order 1200857
Quantity 175,000 KG

Manufacturing date 03/03/2020
Re-test date 16/12/2024
Certificate Nr. 100000009272
Batch Size 850,000 KG
Ref. Order 2020 - 1 / 144

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
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	%	0,03
Residue on ignition	EP 2.4.14 USP <281	<=0,1	%	0,06
Appearance of solution Y6	EP(2.2.1)/(2.2.2)	Clear and not more coloured than Y6		Clear and not more coloured than Y6
Related substances (HPLC): 2,4-Diamine-6-ChloroPyrimidine (impurity B)	EP 2.2.29	<= 0,15	%	< 0,05
Related substances (HPLC): 2,4-Diamine-6-Piperidinpyrimidine (impurity E or deoxyminoxidil)	EP 2.2.29	<=0,2	%	< 0,05
Related substances (HPLC): unspecified impurities	EP 2.2.29	<= 0,10	%	< 0,05
Related substances (HPLC): total impurities by EP	EP 2.2.29	<=0,3	%	< 0,05
Organic impurities: total impurities by USP	USP	<=0,3	%	0,08
Assay (HPLC) (on dried basis)	USP	97,0 - 103,0	%	100,1
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	100,6
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

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

Angelo Cavicchioli
QC Manager
Approved March 26, 2020

Donatella Magani
Qualified Person
Released March 26, 2020

Emission April 30, 2020

Capitale Sociale € 40.000.000 I.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - R.E.A. Milano n. 1201640
Società Capogruppo P. & R. Principi Attivi S.p.A
Società con Socio unico - Strada Rivoltana km. 6/7 - 20090 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v. - C.F. e P.IVA 11155530

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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 March 26, 2020

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Particle size distribution

Measurement Details

Operator Name Righini
Sample Name Average of 'MINOXIDIL'
SOP File Name Minoxidil.msop
Code 17150
Batch 2020000499

Measurement Details

Analysis Date Time 10/03/2020 09:25:46
Measurement Date Time 10/03/2020 09:25:46
Result Source Averaged

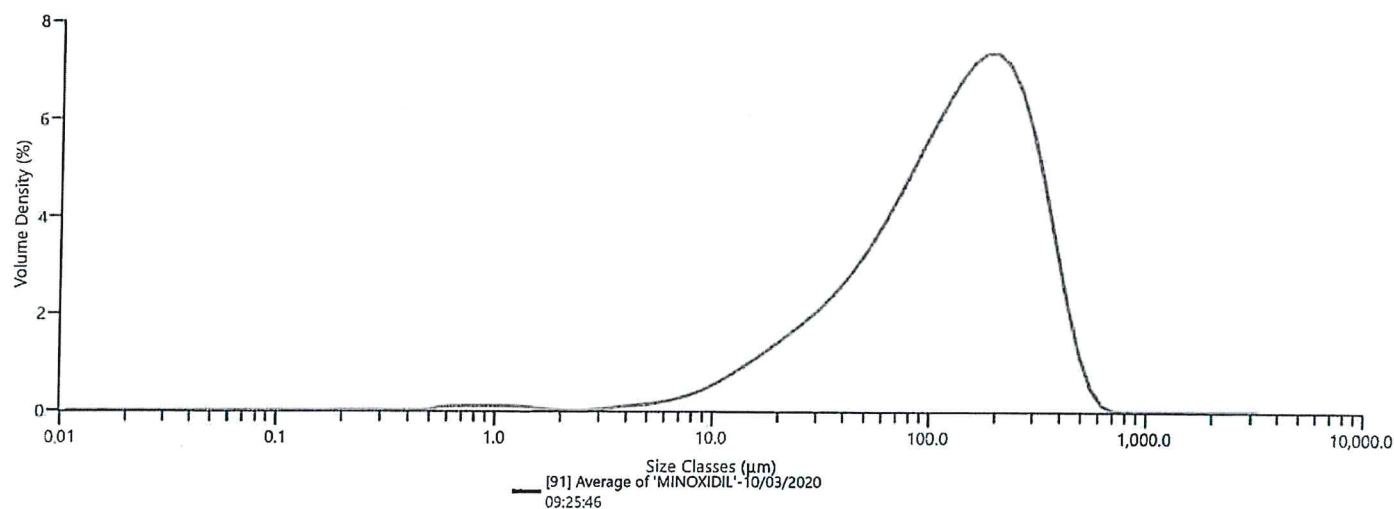
Analysis

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 0.34 %
Laser Obscuration 15.20 %

Result

Concentration 0.0934 %
Span 2.217
Uniformity 0.689
Specific Surface Area 132.9 m²/kg
D [3,2] 43.000 µm
D [4,3] 151.624 µm
Dv (10) 27.447 µm
Dv (50) 127.858 µm
Dv (90) 310.866 µm

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	Size (µm)	% Volume Under
0.010	0.00	0.077	0.00	0.594	0.07	4.583	0.91	35.335	13.51	272.430	85.03	2100.416	100.00
0.011	0.00	0.088	0.00	0.675	0.14	5.207	1.02	40.146	15.60	309.525	89.87	2386.415	100.00
0.013	0.00	0.100	0.00	0.767	0.22	5.916	1.15	45.613	17.95	351.670	93.60	2711.357	100.00
0.015	0.00	0.113	0.00	0.872	0.30	6.722	1.32	51.023	20.59	399.555	96.69	3080.544	100.00
0.017	0.00	0.128	0.00	0.991	0.39	7.637	1.55	58.080	23.57	453.960	98.55	3500.000	100.00
0.019	0.00	0.146	0.00	1.125	0.47	8.677	1.84	66.897	26.90	515.772	99.54		
0.022	0.00	0.165	0.00	1.279	0.54	9.858	2.22	76.006	30.62	586.001	99.92		
0.024	0.00	0.188	0.00	1.453	0.61	11.201	2.71	86.355	34.74	665.793	100.00		
0.028	0.00	0.214	0.00	1.651	0.68	12.726	3.31	98.114	39.28	756.449	100.00		
0.032	0.00	0.243	0.00	1.875	0.68	14.450	4.05	111.473	44.23	859.450	100.00		
0.036	0.00	0.276	0.00	2.131	0.68	16.427	4.93	126.652	49.58	976.475	100.00		
0.041	0.00	0.314	0.00	2.421	0.68	18.664	5.96	143.897	55.27	1109.435	100.00		
0.046	0.00	0.357	0.00	2.750	0.68	21.205	7.13	163.490	61.25	1260.499	100.00		
0.053	0.00	0.405	0.00	3.125	0.70	24.092	8.47	185.752	67.39	1432.133	100.00		
0.060	0.00	0.460	0.00	3.550	0.74	27.373	9.95	211.044	73.54	1627.136	100.00		
0.068	0.00	0.523	0.00	4.034	0.82	31.100	11.64	239.780	79.51	1848.692	100.00		

Particle size distribution

Signature_

Record Number	Sample Name	Signature State	Signatory	Signature Date
91	Average of 'MINOXIDIL'	Unlocked	DESKTOP-2NC0HTJ\Righini	10/03/2020 09:48:08 +01:00
		Locked	DESKTOP-2NC0HTJ\Cersosimo	10/03/2020 09:52:45 +01:00