



Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2120002685
Order 1210694
Quantity 300,000 KG

Manufacturing date 11/09/2021
Re-test date 09/09/2026
Certificate Nr. 100000018612
Batch Size 713,000 KG
Ref. Order 2021 2318

<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
Identification (HPLC)	M> USP	Complies		Complies
Loss on drying	EP 2.2.32	<=0,5	%	0,10
Residue on ignition	EP 2.4.14 USP < 281	<=0,1	%	0,09
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) + 2,4-diamino-5,6-dichloropyrimidine-3-oxide	EP 2.2.29	<=0,10	%	< LOD (0,004)
Related substances (HPLC): 2,4-Diamine-6-Piperidinopyrimidine (impurity E or deoxyminoxidil)	EP 2.2.29	<=0,2	%	< LOQ (0,022)
Related substances (HPLC): unspecified impurities	EP 2.2.29	<=0,10	%	0,011
Related substances (HPLC): total impurities by EP	EP 2.2.29	<=0,3	%	0,052
Organic impurities (HPLC): Pyrimidine oxide analog	USP	<=0,2	%	< 0,05
Organic impurities (HPLC): Pyrimidine analog	USP	<=0,2	%	< 0,05
Organic impurities (HPLC): Deoxyminoxidil	USP	<=0,2	%	< 0,05
Organic impurities (HPLC): Any individual unspecified impurity	USP	<=0,1	%	< 0,05
Organic impurities (HPLC): Total impurities by USP	USP	<=0,3	%	< 0,05
Assay (HPLC)	USP	97,0 - 103,0	%	100,3
Angelo Cavicchioli QC Manager Approved September 23, 2021	Laura Berra Qualified Person Released September 24, 2021			
'Emission'	Donatella Magani	Qualified Person	October 08, 2021	

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 / 5

October 08, 2021

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

October 08, 2021

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(on dried basis)				
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	99,7
Residual solvents (GC): acetone	Internal Method	<= 1000	ppm	69
Residual solvents (GC): Isopropyl Alcohol	Internal Method	<= 2000	ppm	211
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.

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 September 23, 2021	Laura Berra Qualified Person Released September 24, 2021
'Emission'	Donatella Magani Qualified Person October 08, 2021

Measurement Details

Operator Name Righini
Sample Name Average of 'MINOXIDIL'
SOP File Name Minoxidil.msop
Code 17150
Batch 2120002685
Bulk lot type

Measurement Details

Analysis Date Time 16/09/2021 11:26:03
Measurement Date Time 16/09/2021 11:26:03
Result Source Averaged

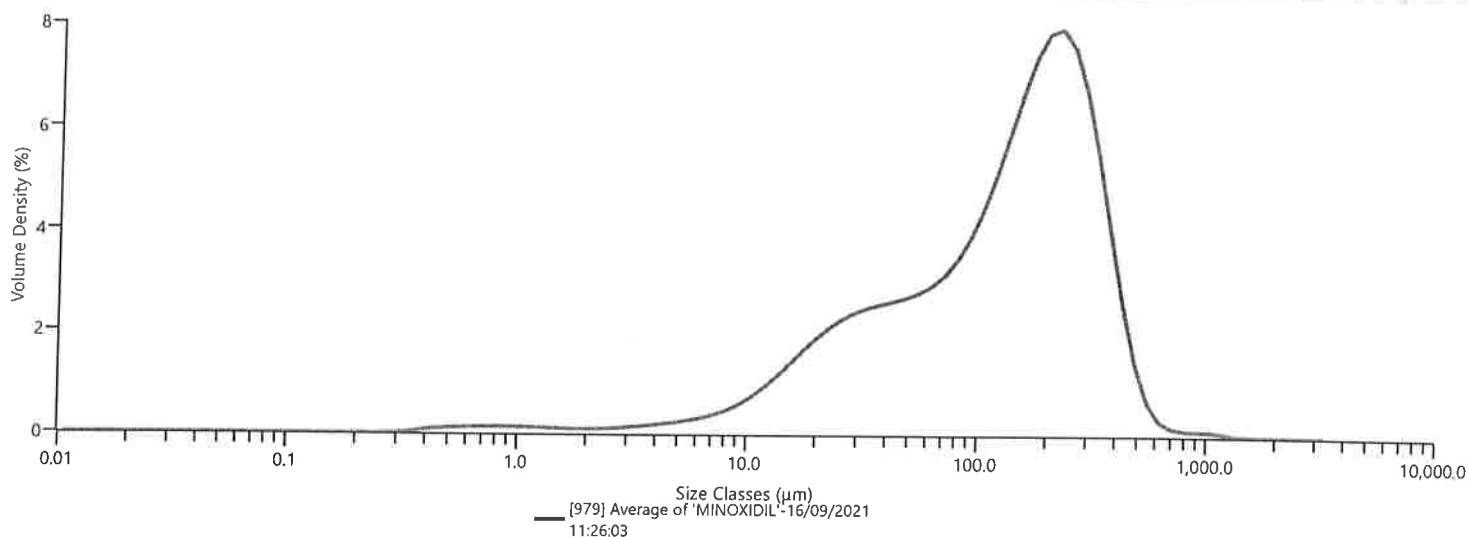
Analysis

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 0.55 %
Laser Obscuration 16.50 %

Result

Concentration 0.0688 %
Span 2.190
Uniformity 0.709
Specific Surface Area 201.9 m²/kg
D [3,2] 28.308 µm
D [4,3] 161.073 µm
Dv (10) 20.718 µm
Dv (50) 141.004 µm
Dv (90) 329.522 µm
Volume In Range (0,25) µm 12.57 %
Volume In Range (0,75) µm 31.58 %
Volume Below (5) µm 2.14 %
Volume Below (20) µm 9.57 %

Frequency (compatible)



Particle size distribution

OLON S.p.A.



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	0.068	0.00	0.460	0.15	3.125	1.58	21.205	10.28	143.897	50.78	976.475	99.88
0.011	0.00	0.077	0.00	0.523	0.24	3.550	1.70	24.092	12.02	163.490	56.37	1109.435	99.95
0.013	0.00	0.088	0.00	0.594	0.33	4.034	1.84	27.373	13.90	185.752	62.54	1260.499	100.00
0.015	0.00	0.100	0.00	0.675	0.44	4.583	2.01	31.100	15.90	211.044	69.12	1432.133	100.00
0.017	0.00	0.113	0.00	0.767	0.55	5.207	2.20	35.335	17.97	239.780	75.78	1627.136	100.00
0.019	0.00	0.128	0.00	0.872	0.66	5.916	2.42	40.146	20.10	272.430	82.13	1848.692	100.00
0.022	0.00	0.146	0.00	0.991	0.77	6.722	2.69	45.613	22.27	309.525	87.76	2100.416	100.00
0.024	0.00	0.166	0.00	1.125	0.88	7.637	3.00	51.823	24.51	351.670	92.33	2386.415	100.00
0.028	0.00	0.188	0.00	1.279	0.98	8.677	3.39	58.880	26.82	399.555	95.65	2711.357	100.00
0.032	0.00	0.214	0.00	1.453	1.07	9.858	3.87	66.897	29.25	453.960	97.77	3080.544	100.00
0.036	0.00	0.243	0.00	1.651	1.15	11.201	4.48	76.006	31.85	515.772	98.90	3500.000	100.00
0.041	0.00	0.276	0.00	1.875	1.23	12.726	5.25	86.355	34.71	586.001	99.41		
0.046	0.00	0.314	0.00	2.131	1.31	14.458	6.20	98.114	37.92	665.793	99.62		
0.053	0.00	0.357	0.02	2.421	1.39	16.427	7.36	111.473	41.61	756.449	99.72		
0.060	0.00	0.405	0.07	2.750	1.47	18.664	8.72	126.652	45.87	859.450	99.81		

Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
979	Average of 'MINOXIDIL'	Unlocked	DESKTOP-2NC0HTJ\Righini	16/09/2021 11:28:04 +02:00
		Locked	DESKTOP-2NC0HTJ\Gerosa	16/09/2021 11:36:13 +02:00

