



METAPHARMACEUTICAL

N DE LOTE:

0100921

Certificate of Analysis

09/09/2021

Product name MINOXIDIL EP/USP

Product Code 17150
Batch Number 2120002373
Order 1211360
Quantity 100,000 KG

Manufacturing date 26/07/2021
Re-test date 21/07/2026
Certificate Nr. 100000018022
Batch Size 765,000 KG
Ref. Order 2021-1/296

Test	References	Specification	M.U.	Result
Appearance	EP	White or almost white cry stalline 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	%	0,01
Residue on ignition	EP 2.4.14 USP < 281	<=0,1	%	0,07
Appearance of solution Y6	EP(2.2.1)/(2.2.2)	Clear and not more colour ed 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	%	< LOD (0,004)
Related substances (HPLC): 2,4-Diamine-6-Piperidinpyrimidine (impurity E or deoxyminoxidil)	EP 2.2.29	<=0,2	%	< LOD (0,007)
Related substances (HPLC): unspecified impurities	EP 2.2.29	<=0,10	%	< LOQ (0,020)
Related substances (HPLC): total impurities by EP	EP 2.2.29	<=0,3	%	0,020
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	%	100,4

Angelo Cavicchioli QC Manager Approved August 26, 2021	Donatella Magani Qualified Person Released August 26, 2021
'Emission'	Laura Berra Qualified Person September 03, 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

September 03, 2021

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

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<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
(on dried basis)				
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	100,1
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.

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

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

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Particle size distribution

OLON S.p.A.



Measurement Details

Operator Name Righini
Sample Name Average of 'MINOXIDIL'
SOP File Name Minoxidil.msop
Code 17150
Batch 2120002373
Bulk lot type

Measurement Details

Analysis Date Time 02/08/2021 11:27:37
Measurement Date Time 02/08/2021 11:27:37
Result Source Averaged

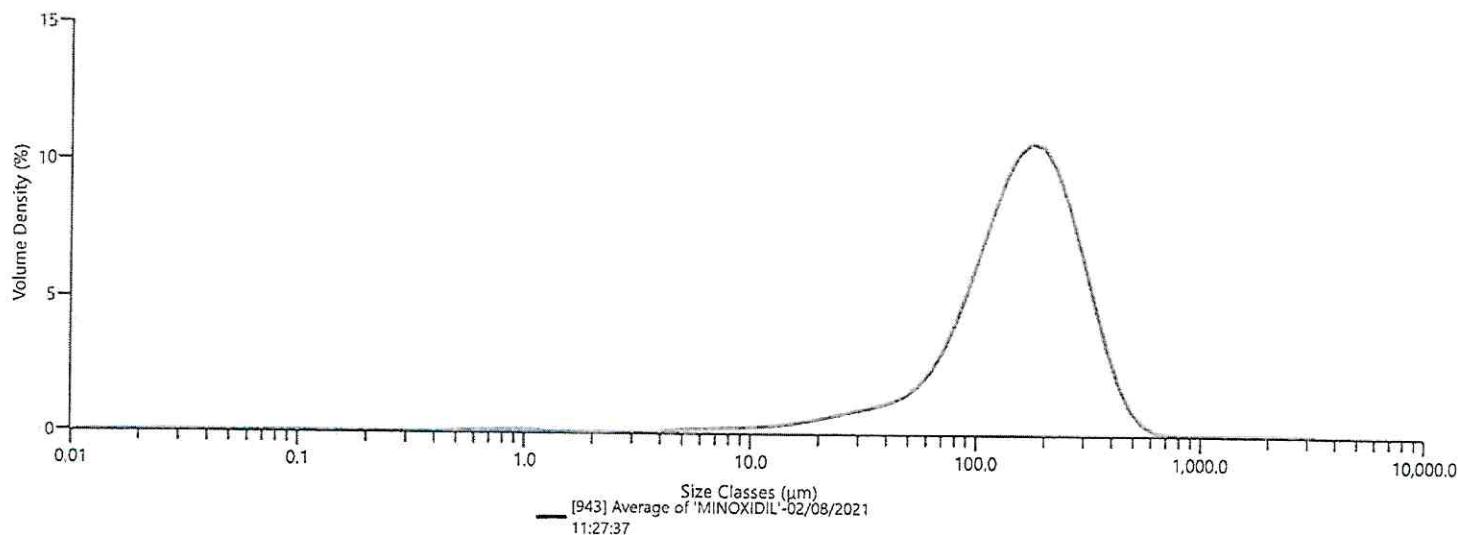
Analysis

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 0.58 %
Laser Obscuration 13.69 %

Result

Concentration 0.1426 %
Span 1.545
Uniformity 0.477
Specific Surface Area 81.20 m²/kg
D [3,2] 70.371 µm
D [4,3] 174.528 µm
Dv (10) 59.492 µm
Dv (50) 160.392 µm
Dv (90) 307.298 µm
Volume In Range (0,25) µm 3.49 %
Volume In Range (0,75) µm 14.06 %
Volume Below (5) µm 0.43 %
Volume Below (20) µm 2.60 %

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	0.00	3.125	0.33	21.205	2.80	143.897	42.65	976.475	100.00
0.011	0.00	0.077	0.00	0.523	0.00	3.550	0.33	24.092	3.32	163.490	51.30	1109.435	100.00
0.013	0.00	0.088	0.00	0.594	0.04	4.034	0.33	27.373	3.92	185.752	60.30	1260.499	100.00
0.015	0.00	0.100	0.00	0.675	0.09	4.583	0.37	31.100	4.60	211.044	69.16	1432.133	100.00
0.017	0.00	0.113	0.00	0.767	0.14	5.207	0.46	35.335	5.37	239.780	77.40	1627.136	100.00
0.019	0.00	0.128	0.00	0.872	0.19	5.916	0.55	40.146	6.24	272.430	84.56	1848.692	100.00
0.022	0.00	0.146	0.00	0.991	0.24	6.722	0.67	45.613	7.22	309.525	90.33	2100.416	100.00
0.024	0.00	0.166	0.00	1.125	0.29	7.637	0.79	51.823	8.38	351.670	94.57	2386.415	100.00
0.028	0.00	0.188	0.00	1.279	0.33	8.677	0.93	58.880	9.84	399.555	97.35	2711.357	100.00
0.032	0.00	0.214	0.00	1.453	0.33	9.858	1.09	66.897	11.76	453.960	98.92	3080.544	100.00
0.036	0.00	0.243	0.00	1.651	0.33	11.201	1.27	76.006	14.33	515.772	99.64	3500.000	100.00
0.041	0.00	0.276	0.00	1.875	0.33	12.726	1.48	86.355	17.76	586.001	99.93		
0.046	0.00	0.314	0.00	2.131	0.33	14.458	1.72	98.114	22.25	665.793	100.00		
0.053	0.00	0.357	0.00	2.421	0.33	16.427	2.01	111.473	27.91	756.449	100.00		
0.060	0.00	0.405	0.00	2.750	0.33	18.664	2.37	126.652	34.76	859.450	100.00		

Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
943	Average of 'MINOXIDIL'	Unlocked	DESKTOP-2NCOHTJ\Righini	02/08/2021 11:29:08 +02:00
		Locked	DESKTOP-2NCOHTJ\Cavicchioli	26/08/2021 11:10:26 +02:00

