



Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2020000309
Order 1192811
Quantity 100,000 KG

Manufacturing date 13/02/2020
Re-test date 14/01/2025
Certificate Nr. 100000008029
Batch Size 825,000 KG
Ref. Order 2019 - 1/461

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
Appearance	EP	White or almost white crystalline powder		Almost white crystalline powder
Identification (IR)	EP (2.2.24)/USP <197	IR spectrum conforms to standard		Complies
Loss on drying	EP 2.2.32	<=0,5	%	0,12
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	%	0,06
Assay (HPLC) (on dried basis)	USP	97,0 - 103,0	%	100,0
Assay (HClO ₄) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	99,9
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 February 25, 2020

Donatella Magani
Qualified Person
Released February 25, 2020

Emission February 26, 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 del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società capogruppo P. & R. S.p.A.
Strada Rivoltana Km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 I.v. - C.F. e P.I. 00651030181

Modello: 17150-STD / 2



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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 February 25, 2020

Donatella Magani
Qualified Person
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Measurement Details

Operator Name Righini
Sample Name Average of 'MINOXIDIL'
SOP File Name Minoxidil.msop
Code 17150
Batch 2020000309

Measurement Details

Analysis Date Time 13/02/2020 12:23:06
Measurement Date Time 13/02/2020 12:23:06
Result Source Averaged

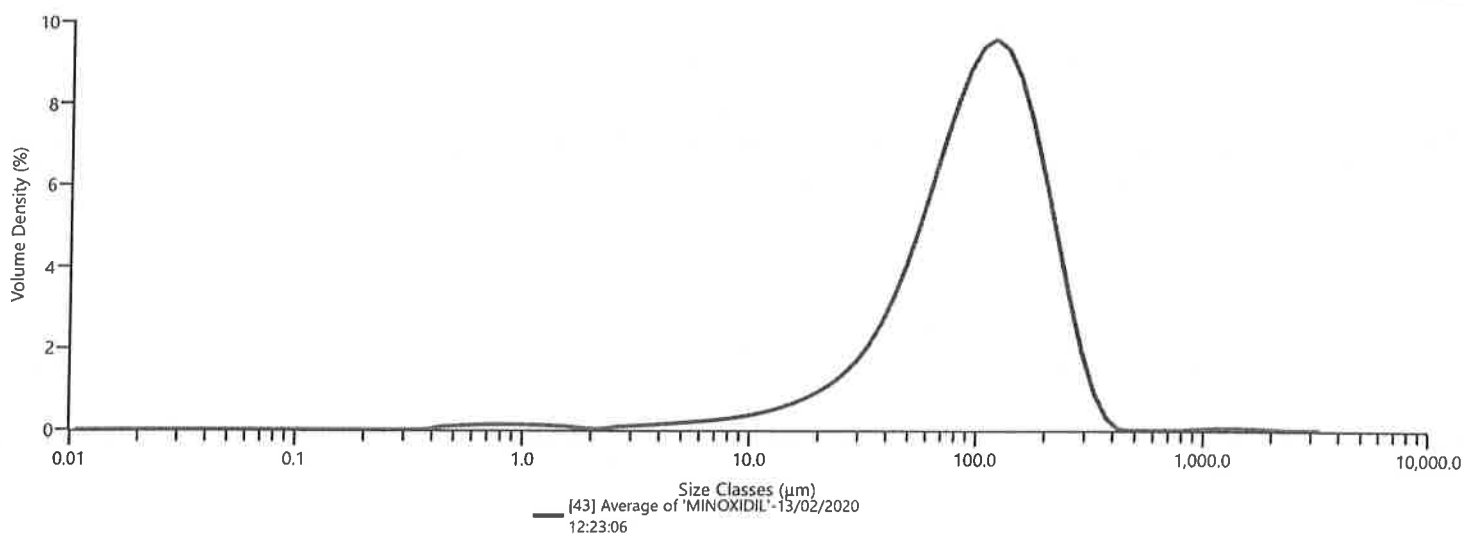
Analysis

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 0.19 %
Laser Obscuration 14.13 %

Result

Concentration 0.0681 %
Span 1.729
Uniformity 0.556
Specific Surface Area 169.4 m²/kg
D [3,2] 33.726 µm
D [4,3] 114.755 µm
Dv (10) 32.812 µm
Dv (50) 101.047 µm
Dv (90) 207.565 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
0.010	0.00	0.077	0.00	0.594	0.23	4.583	1.55	35.335	11.00	272.430	97.26
0.011	0.00	0.088	0.00	0.675	0.32	5.207	1.69	40.146	13.14	309.525	98.82
0.013	0.00	0.100	0.00	0.767	0.43	5.916	1.84	45.613	15.83	351.670	99.55
0.015	0.00	0.113	0.00	0.872	0.54	6.722	2.02	51.823	19.18	399.555	99.77
0.017	0.00	0.128	0.00	0.991	0.65	7.637	2.23	58.880	23.30	453.960	99.77
0.019	0.00	0.146	0.00	1.125	0.75	8.677	2.46	66.897	28.27	515.772	99.77
0.022	0.00	0.166	0.00	1.279	0.84	9.858	2.73	76.006	34.12	586.001	99.77
0.024	0.00	0.188	0.00	1.453	0.92	11.201	3.05	86.355	40.80	665.793	99.77
0.028	0.00	0.214	0.00	1.651	1.00	12.726	3.42	98.114	48.19	756.449	99.77
0.032	0.00	0.243	0.00	1.875	1.04	14.458	3.87	111.473	56.05	859.450	99.77
0.036	0.00	0.276	0.00	2.131	1.06	16.427	4.41	126.652	64.07	976.475	99.79
0.041	0.00	0.314	0.00	2.421	1.08	18.664	5.05	143.897	71.89	1109.435	99.83
0.046	0.00	0.357	0.00	2.750	1.15	21.205	5.83	163.490	79.14	1260.499	99.87
0.053	0.00	0.405	0.00	3.125	1.23	24.092	6.76	185.752	85.48	1432.133	99.91
0.060	0.00	0.460	0.06	3.550	1.32	27.373	7.89	211.044	90.68	1627.136	99.95
0.068	0.00	0.523	0.14	4.034	1.42	31.100	9.28	239.780	94.59	1848.692	99.98

Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
43	Average of 'MINOXIDIL'	Unlocked	DESKTOP-2NC0HTJ\Righini	13/02/2020 12:32:04 +01:00
		Locked	DESKTOP-2NC0HTJ\Cersosimo	13/02/2020 12:35:39 +01:00