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

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Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
20053 Rodano (MI)

METAPHARMACEUTICAL

N DE LOTE:
01107 22

Certificate of Analysis

18/07/2022

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2220001266
Batch Size 900,000 KG

Manufacturing date 06/05/2022
Re-test date 04/05/2027
Certificate Nr. 890000011124

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 M>	IR spectrum conforms to standard		Complies
Identification (HPLC)	USP	Complies		Complies
Loss on drying	EP 2.2.32	<=0,5	%	0,03
Residue on ignition	EP 2.4.14 USP < 281 >	<=0,1	%	0,04
Appearance of solution	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-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	%	0,015
Organic impurities (HPLC): Pyrimidine oxide analog	USP	<=0,2	%	< LOD (0,002)
Organic impurities (HPLC): Pyrimidine analog	USP	<=0,2	%	0,01
Organic impurities (HPLC): Deoxyminoxidil	USP	<=0,2	%	< LOD (0,013)
Organic impurities (HPLC): Any individual unspecified impurity	USP	<=0,1	%	< LOQ (0,022)
Organic impurities (HPLC): Total impurities by USP	USP	<=0,3	%	0,02
Assay (HPLC)	USP	97,0 - 103,0	%	99,3

Silvana Zanetta

Approved July 12, 2022

Laura Berra
Qualified Person
Approved July 12, 2022

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(on dried basis)				
Assay (HClO) (on dried basis)	EP (2.2.20)	99,0 - 101,0	%	100,5
Residual solvents (GC): acetone	Internal Method	<= 1000	ppm	< LOQ (60)
Residual solvents (GC): Isopropyl Alcohol	Internal Method	<= 2000	ppm	< LOD (45)
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.

Silvana Zanetta Approved July 12, 2022	Laura Berra Qualified Person Approved July 12, 2022