lot: 011052

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)

Certificate of Analysis

Product name **MINOXIDIL EP/USP**

Product Code 17150
Batch Number 2120000390
Batch Size 837,000 KG

Manufacturing date 09/02/2021
Re-test date 02/02/2026
Certificate Nr. 040000033578

Test	References	Specification	M.U.	Result
Appearance	EP	White or almost white crystalline powder		Almost 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	%	0,10
Residue on ignition	EP 2.4.14 USP <281>	<=0,1	%	0,08
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-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	%	0,017
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	%	0,13
Organic impurities (HPLC): Any individual unspecified impurity	USP	<=0,1	%	0,07
Organic impurities (HPLC): Total impurities by USP	USP	<=0,3	%	0,21
Assay (HPLC)	USP	97,0 - 103,0	%	100,1

Angelo Cavicchioli
QC Manager
Approved February 24, 2021

Donatella Magani
Qualified Person
Released February 24, 2021

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Test	References	Specification	M.U.	Result
(on dried basis)				
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.

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 24, 2021	Donatella Magani Qualified Person Released February 24, 2021