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
20053 Rodano (MI)

METAPHARMACEUTICAL

N DE LOTE: 2101024 07/10/2024

# Certificate of Analysis

| | | | |
|---|---|---|---|
| Product name | **MINOXIDIL EP/USP** | | |
| | | Manufacturing date | 04/07/2024 |
| Product Code | 17150 | Re-test date | 01/05/2029 |
| Batch Number | 0024201942 | Certificate Nr. | 100000035852 |
| Order | 1240815 | Batch Size | 1.071,000 KG |
| Quantity | 350,000 KG | Ref. Order | 2024 - 1 / 187 |

| 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 | <= 0,50 | % | < 0,10 |
| Residue on ignition | EP 2.4.14 USP < 281 > | <= 0,10 | % | 0,10 |
| Appearance of solution Y6 | EP(2.2.1)/(2.2.2) | Clear and not more colored 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 | <= 0,100 | % | not detectable |
| Related substances (HPLC): 2,4-Diamine-6-Piperidinpyrimidine (impurity E or deoxyminoxidil) | EP 2.2.29 | <= 0,20 | % | < LOD (0,007) |
| Related substances (HPLC): unspecified impurities | EP 2.2.29 | <= 0,100 | % | < LOQ (0,020) |
| Related substances (HPLC): total impurities by EP | EP 2.2.29 | <= 0,300 | % | <0,1% (0,02%) |
| Organic impurities (HPLC): Pyrimidine oxide analog | USP | <= 0,20 | % | not detectable |
| Organic impurities (HPLC): Pyrimidine analog | USP | <= 0,20 | % | not detectable |
| Organic impurities (HPLC): Deoxyminoxidil | USP | <= 0,20 | % | < LOD (0,013) |
| Organic impurities (HPLC): Any individual unspecified impurity | USP | <= 0,10 | % | < LOD (0,009) |
| Organic impurities (HPLC): Total impurities by USP | USP | <= 0,30 | % | <0,1% (0,007%) |
| Assay (HPLC) | USP | 97,0 - 103,0 | % | 100,1 |

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|---|---|---|---|
| Ivo Zanotti<br>QC Manager<br>Approved September 27, 2024 | Laura Berra<br>Qualified Person<br>Released September 27, 2024 | | |
| 'Emission' | Laura Berra | Qualified Person | September 30, 2024 |

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|---|---|---|---|---|
| (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 | < LOD (25) |
| 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.**

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