



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215294

| | |
|-------------------|------------------|
| Product: | MINOXIDIL |
| Lot: | 215294 |
| Expiry date: | 01/09/2026 |
| Reference: | Cumple PhEur10.5 |
| Synonyms: | |
| Formula: | C9H15N5O |
| Molecular weight: | 209,25 g/mol |

| Assay | Result | Specification | |
|-----------------------------|-------------|----------------|---|
| Identification | Conform (B) | Test PhEur (B) | |
| Organoleptic properties | Conform | PhEur | |
| Heavy metals | <= 20 ppm | <= 20 ppm | # |
| Related substances (HPLC) | Conform | | = |
| Loss on drying (1 g, 105°C) | 0,05 % | <= 0,5% | |
| Sulphated ashes | <= 0,1 % | <= 0,1 % | = |
| Assay | 100,2 % | 99,0 - 101,0 % | |
| Impurity B | <= 0,05 % | <= 0,15 % | = |
| Impurity E | <= 0,05 % | <= 0,2 % | = |
| Unspecified Impurities | <= 0,05 % | <= 0,10 % | = |
| Total impurities | <= 0,3 % | <= 0,3 % | = |
| Residual solvent: Methanol | <= 3000 ppm | <= 3000 ppm | # |

Organoleptic characteristics: White or almost white crystalline powder. Slightly soluble in water, soluble in methanol and in propylene glycol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 06/10/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01009 TRIFARMA SpA

Manufacturer batch: 321065

| Product | Name | Capacity | Batch |
|---------|------------------|----------|------------|
| 1160665 | MINOXIDILO | 25 g | 215294-G-1 |
| 1160667 | MINOXIDILO | 100 g | 215294-J-2 |
| 1160668 | MINOXIDILO | 250 g | 215294-N-2 |
| 1160670 | MINOXIDILO | 1 kg | 215294-P-2 |
| 1370204 | MINOXIDILO (FLB) | 100 g | 215294-J-1 |

| | | | |
|---------|-----------------------------|-------|------------|
| 1370205 | MINOXIDILO (FLB) | 250 g | 215294-N-1 |
| 1370206 | MINOXIDILO (FLB) (INACTIVO) | 500 g | 215294-O-1 |
| 1370207 | MINOXIDILO (FLB) | 1 kg | 215294-P-1 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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