

## Minoxidil

|   |  |   |
|---|--|---|
| <b>CODE ARTICLE:</b><br>97472   | <b>BATCH:</b><br>0120256               | <b>Active pharmaceutical ingredient</b> |
| <b>TEST DATE:</b><br>26/06/2023   | <b>TEST:</b><br>QC-00254655            |   |
| <b>EXPIRY DATE:</b><br>13/03/2028   | <b>FABRICATION DATE:</b><br>09/04/2023 | <b>MR:</b><br>209,30                    |
| <b>CAS:</b><br>[38304-91-5]   | <b>FORMULA:</b><br>C9H15N5O            |   |
| <b>SYNONYMS / BOTANICAL NAME:</b><br>Minoxidilo                             |  |   |
| <b>STORAGE:</b><br>Store in tightly closed containers in a cool, dry place. |  |   |

| TEST  | RESULTS                   | Units | MIN | MAX   | METHOD                 |
|---|---------------------------|-------|-----|---|------------------------|
| APPEARANCE                                  | CONFORM                   | -     |     | POLVO<br>CRISTAL<br>BLANCO O<br>CASI BLANCO | PH.EUR.*               |
| COLOUR                                      | CONFORM                   | -     |     | BLANCO                                      | PH.EUR.*               |
| <u>SOLUBILITY</u>                           |                           |       |     |   |                        |
| SOLUBLE                                     | METHANOL                  |       |     |   | PH.EUR.*               |
| SOLUBLE                                     | PROPYLENE GLYCOL          |       |     |   | PH.EUR.*               |
| SOLUBLE                                     | SLIGHTLY SOLUBLE IN WATER |       |     |   | PH.EUR.*               |
| <u>IDENTIFICATION</u>                       |                           |       |     |   |                        |
| IR IDENTIFICATION                           | CONFORM                   |       |     |   | PH.EUR.*               |
| <u>RELATED SUBSTANCES</u>                   |                           |       |     |   |                        |
| TOTAL IMPURITIES                            | <RT=0,05 %                |       |     | <=0,3                                       | PH.EUR.*               |
| UNSPECIFIED IMPURITIES                      | <RT=0,05 %                |       |     | <=0,10                                      | PH.EUR.*               |
| IMPURITY B                                  | <RT=0,05 %                |       |     | <=0,15                                      | PH.EUR.*               |
| IMPURITY E                                  | <RT=0,05 %                |       |     | <=0,2                                       | PH.EUR.*               |
| LOSS ON DRYING                              | 0,04 %                    |       |     | <=0,5                                       | PH.EUR.*               |
| SULPHATED ASHES                             | 0,1 %                     |       |     | <=0,1                                       | PH.EUR.*               |
| ASSAY (DRY SUBSTANCE)                       | 100,6 %                   |       | 99  | 101   | PH.EUR.*               |
| <u>RESIDUAL SOLVENTS</u>                    |                           |       |     |   |                        |
| METHANOL                                    | <2 ppm                    |       |     | <=500                                       | Manufacture's Standard |
| RESIDUAL ACETIC ACID                        | 611 MG/KG                 |       |     | <=1000                                      | Manufacture's Standard |
| RESIDUAL ACETONE                            | 9 MG/KG                   |       |     | <=500                                       | Manufacture's Standard |
| SAMPLING                                    | COLLECT                   |       |     |   | Manufacture's Standard |
| CORRECT BATCH                               | YES                       |       |     |   | Manufacture's Standard |
| SPECIFICATION                               | PH.EUR 11                 |       |     |   | Manufacture's Standard |
| Risk Assessment Evaluation for Nitrosamines | PASS                      | -     |     |   | Manufacture's Standard |
| Elemental Impurities ICHQ3D                 | PASS                      | -     |     |   | Manufacture's Standard |

*This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.*

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.



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|------|---------|-------|-----|-----|--------|
|------|---------|-------|-----|-----|--------|



**Este producto ha sido manipulado en sala NO estéril, para lotes aptos uso estéril consultar disponibilidad.**

**Silvia Sancho-Tello Ripoll**  
Technical Director.

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