

## Fluocinolone acetonide

|   |  |   |
|---|--|---|
| <b>CODE ARTICLE:</b><br>93950   | <b>BATCH:</b><br>0118447   | <b>Active pharmaceutical ingredient</b> |
| <b>TEST DATE:</b><br>25/10/2022   | <b>TEST:</b><br>QC-00246996  |   |
| <b>EXPIRY DATE:</b><br>07/07/2027   | <b>FABRICATION DATE:</b><br>07/07/2022   | <b>MR:</b><br>452,50                    |
| <b>CAS:</b><br>[67-73-2]  | <b>FORMULA:</b><br>C <sub>24</sub> H <sub>30</sub> F <sub>2</sub> O <sub>6</sub> |   |
| <b>STORAGE:</b><br>Store in tightly closed containers in a cool, dry place. |  |   |

| TEST                             | RESULTS                        | Units | MIN    | MAX                                  | METHOD                 |
|----------------------------------|--------------------------------|-------|--------|--------------------------------------|------------------------|
| APPEARANCE                       | CONFORM                        | -     |        | White or almost white crystal powder | PH.EUR.*               |
| COLOUR                           | CONFORM                        | -     |        | White                                | PH.EUR.*               |
| <u>SOLUBILITY</u>                |                                |       |        |                                      |                        |
| SOLUBLE                          | ANHIDROUS ETHANOL              |       |        |                                      | PH.EUR.*               |
| SOLUBLE                          | IN ACETONE                     |       |        |                                      | PH.EUR.*               |
| INSOLUBLE                        | WATER                          |       |        |                                      | PH.EUR.*               |
| INSOLUBLE                        | HEPTANO                        |       |        |                                      | PH.EUR.*               |
| SOLUBLE                          | METHANOL                       |       |        |                                      | Manufacture's Standard |
| SOLUBLE                          | SLIGHTLY SOLUBLE IN CHLOROFORM |       |        |                                      | Manufacture's Standard |
| SOLUBLE                          | SLIGHTLY SOLUBLE IN ETHER      |       |        |                                      | Manufacture's Standard |
| <u>IDENTIFICATION</u>            |                                |       |        |                                      |                        |
| IR IDENTIFICATION                | CONFORM                        |       |        |                                      | PH.EUR.*               |
| IDENTIFICATION (HPLC)            | CONFORM                        |       |        |                                      | PH.EUR.*               |
| SPECIFIC ROTATION                | 102 DEGREES                    |       | 100    | 104                                  | PH.EUR.*               |
| SPECIFIC ROTATION                | 104,3 DEGREES                  |       | 98     | 108                                  | USP                    |
| <u>RELATED SUBSTANCES (HPLC)</u> |                                |       |        |                                      |                        |
| TOTAL IMPURITIES                 | 0,12 %                         |       |        | <=0,7                                | PH.EUR.*               |
| UNSPECIFIED IMPURITIES           | <RT (0,05%) %                  |       |        | <=0,10                               | PH.EUR.*               |
| IMPURITY D                       | <RT (0,05%) %                  |       |        | <=0,2                                | PH.EUR.*               |
| IMPURITY H                       | <RT (0,05%) %                  |       |        | <=0,15                               | PH.EUR.*               |
| IMPURITY I                       | 0,12 %                         |       |        | <=0,15                               | PH.EUR.*               |
| IMPURITY J                       | <RT (0,05%) %                  |       |        | 0,2                                  | PH.EUR.*               |
| IMPURITY K                       | N.D. %                         |       |        | 0,3                                  | PH.EUR.*               |
| LOSS ON DRYING                   | 0,3 %                          |       |        | <=1,0                                | PH.EUR.*               |
| ASSAY (HPLC) (DRY BASIS).        | 99,2 %                         |       | 97,5   | 102                                  | PH.EUR.*               |
| ASSAY (SPECTROPHOTOMETRY)        | 99,8 %                         |       | 97     | 102                                  | Manufacture's Standard |
| <u>RESIDUAL SOLVENTS</u>         |                                |       |        |                                      |                        |
| METHANOL                         | 3 ppm                          |       |        | <=500                                | Manufacture's Standard |
| ACETONE                          | 36 ppm                         |       |        | <=1000                               | Manufacture's Standard |
| METHYLENE CHLORIDE               | N.D. ppm                       |       |        | <=500                                | Manufacture's Standard |
| <u>PARTICLE SIZE</u>             |                                |       |        |                                      |                        |
| PARTICLE SIZE <30 MICRAS         | 100,0 %                        |       | >=99,0 |                                      | Manufacture's Standard |

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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| <b>CAS:</b><br>[67-73-2]  | <b>FORMULA:</b><br>C24H30F2O6          |   |
| <b>STORAGE:</b><br>Store in tightly closed containers in a cool, dry place. |  |   |

| TEST  | RESULTS        | Units | MIN    | MAX | METHOD                 |
|---|----------------|-------|--------|-----|------------------------|
| PARTICLE SIZE <15 MICRAS                    | 100,0 %        |       | >=95,0 |     | Manufacture's Standard |
| PARTICLE SIZE <5 MICRAS                     | 84,1 %         |       | >=75,0 |     | Manufacture's Standard |
| ABSORBANCE AT 238nm                         | 354,4 -        |       | 344    | 366 | Manufacture's Standard |
| ORIGIN PACKAGING MATERIAL                   | NATURAL PELD   |       |        |     | Manufacture's Standard |
| CORRECT BATCH                               | YES            |       |        |     | Manufacture's Standard |
| SAMPLING                                    | COLLECT        |       |        |     | Manufacture's Standard |
| SPECIFICATION                               | PH.EUR 10, USP |       |        |     | Manufacture's Standard |
| Risk Assessment Evaluation for Nitrosamines | CONFORM        |       |        |     |                        |
| Elemental Impurities ICHQ3D                 | CONFORM        |       |        |     |                        |

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



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

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