



## Certificate of Analysis

Product name **TRETINOIN - USP/EP Current Edition**

Product Code 2610460  
Batch Number 2210000281  
Order 1221805  
Quantity 0,200 KG

Manufacturing date 10/02/2022  
Re-test date 09/02/2025  
Certificate Nr. 100000024612  
Batch Size 23,135 KG  
Ref. Order WIL 22022080404

| <u>Test</u>                                  | <u>References</u>   | <u>Specification</u>   | <u>M.U.</u> | <u>Result</u>        |
|----------------------------------------------|---------------------|------------------------|-------------|----------------------|
| Appearance                                   | EP / USP            | Crystalline powder     |             | Crystalline powder   |
| Colour                                       | EP / USP            | Yellow or light orange |             | Yellow               |
| IR identification                            | EP2.2.24/USP<197M > | Conforms to standard   |             | Conforms to standard |
| UV identification                            | USP <197U>          | Conforms to standard   |             | Conforms to standard |
| Loss on drying                               | EP2.2.32/USP<731 >  | <= 0,5                 | %           | 0,1                  |
| Residue on ignition                          | EP / USP            | <= 0,1                 | %           | 0,0                  |
| Assay (TBAH)                                 | EP / USP            | 98,0 - 102,0           | % d.b.      | 99,5                 |
| Isotretinoin                                 | Int Val Meth (HPLC) | <= 0,50                | %           | < LOQ (0,01)         |
| Epoxy derivative                             | Int Val Meth (HPLC) | < 0,15                 | %           | < LOQ (0,02)         |
| Impurity a (4-methoxy retinoic acid)         | Int Val Meth (HPLC) | < 0,15                 | %           | 0,04                 |
| Any unspecified impurity                     | Int Val Meth (HPLC) | <= 0,10                | %           | 0,02                 |
| Total impurities (except Isotretinoin)       | Int Val Meth (HPLC) | <= 0,50                | %           | 0,12                 |
| ICH Class 1 solvents : not used              | Int Val Meth (GC)   | Not tested             |             | Not tested           |
| ICH Class 2 solvents                         | Int Val Meth (GC)   | In specific            |             | In specific          |
| Chloroform                                   | Int Val Meth (GC)   | <= 50                  | ppm         | < LOQ (25)           |
| Methyl alcohol                               | Int Val Meth (GC)   | <= 100                 | ppm         | < LOQ (26)           |
| ICH Class 3 solvents                         | Int Val Meth (GC)   | In specific            |             | In specific          |
| Ethyl acetate                                | Int Val Meth (GC)   | <= 100                 | ppm         | 28                   |
| Isopropyl alcohol                            | Int Val Meth (GC)   | <= 2000                | ppm         | 719                  |
| Isotretinoin (EP)                            | EP (HPLC)           | <= 0,50                | %           | < LOQ (0,05)         |
| Epoxy derivative (EP)                        | EP (HPLC)           | < 0,15                 | %           | < LOQ (0,05)         |
| Impurity a (EP)<br>(4-methoxy retinoic acid) | EP (HPLC)           | < 0,15                 | %           | < LOQ (0,05)         |
| Any unspecified impurity (EP)                | EP (HPLC)           | <= 0,10                | %           | < LOQ (0,05)         |
| Total impurities (EP)                        | EP (HPLC)           | <= 0,50                | %           | < LOQ (0,05)         |
| Clarity of solution in chloroform            | Internal Method     | <= 3,0                 | NTU         | 0,3                  |
| Clarity of solution in THF (10%)             | Internal Method     | Clear                  |             | Clear                |

**Packaging and storage: store in airtight containers, in a dry place, protected from light, heat and moisture, at a mean temperature of 25°C (allowed excursions 15-30°C). It is recommended that the contents of an opened container**

|                                                                            |                                                               |
|----------------------------------------------------------------------------|---------------------------------------------------------------|
| Alessandro Paganelli<br>Resp. Laboratorio QM<br>Approved February 28, 2022 | Cosimo Chirivì<br>Qualified Person<br>Released March 03, 2022 |
| 'Emission'                                                                 | Ambra Tesei<br>Qualified Person<br>October 10, 2022           |



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

be used as soon as possible and any unused part be protected under vacuum or under atmosphere of an inert gas.

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A).  
Manufacturing site of the Active Pharmaceutical Ingredient: Olon S.p.A - Garbagnate Milanese

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|                                                                            | October 10, 2022                                              |