



**METAPHARMACEUTICAL**

N DE LOTE:

0071123

## Certificate of Analysis

*af* 15/11/2023

Product name **SODIUM CROMOGLICATE**  
Product Code C4050  
Batch Number 2350000483  
Batch Size 162,000 KG

Manufacturing date 21/02/2023  
Re-test date 26/01/2028  
Certificate Nr. 040000064459

| Test                                                                                                                 | Specification       | M.U. | Result                   |
|----------------------------------------------------------------------------------------------------------------------|---------------------|------|--------------------------|
| DESCRIPTION:<br>white or almost white hygroscopic<br>crystalline powder                                              | complies            |      | complies                 |
| IDENTIFICATION (IR)                                                                                                  | complies            |      | complies                 |
| IDENTIFICATION (UV)                                                                                                  | complies            |      | complies                 |
| IDENTIFICATION (HPLC retention time)                                                                                 | complies            |      | complies                 |
| IDENTIFICATION (sodium reaction)                                                                                     | complies            |      | complies                 |
| ACIDITY/ALKALINITY                                                                                                   | complies to Ph.Eur. |      | complies                 |
| ACIDITY/ALKALINITY                                                                                                   | complies to JP      |      | complies                 |
| APPEARANCE OF SOLUTION:<br>a 2.0% solution in water is not more<br>intensely coloured than reference<br>solution BYs | complies            |      | complies                 |
| CLARITY OF SOLUTION:<br>a 2.0% solution in water is not more<br>opalescent than reference suspension II              | complies            |      | complies                 |
| COLOUR OF SOLUTION:<br>Abs at 440 nm (5.0% solution)                                                                 | <= 0,05             | AU   | 0,02                     |
| WATER                                                                                                                | <= 10,0             | %    | 5,7                      |
| LOSS ON DRYING                                                                                                       | <= 10,0             | %    | 5,5                      |
| OXALATE                                                                                                              | ≤ 0,35 %            |      | ≤ 0,35 %                 |
| --                                                                                                                   | -                   |      | -                        |
| RELATED SUBSTANCES                                                                                                   | -                   |      | -                        |
| Impurity 1 (rel.sub. HPLC)                                                                                           | <= 0,10             | %    | < Disregard limit (0,01) |
| Impurity 2 (rel.sub. HPLC)                                                                                           | <= 0,10             | %    | < Disregard limit (0,01) |
| Impurity 3 (rel.sub. HPLC)                                                                                           | <= 0,10             | %    | < Disregard limit (0,01) |
| Any other Impurity (rel.sub. HPLC)                                                                                   | <= 0,10             | %    | 0,06 (NOTE)              |
| Any other Impurity 1 (rel.sub. HPLC)                                                                                 | <= 0,10             | %    | 0,02 (NOTE)              |
| Any other Impurity 2 (rel.sub. HPLC)                                                                                 | <= 0,10             | %    | 0,02 (NOTE)              |
| Sum of all Impurities (rel.sub. HPLC)                                                                                | <= 0,30             | %    | 0,10                     |
| --                                                                                                                   | -                   |      | -                        |
| RESIDUAL SOLVENTS:                                                                                                   | -                   |      | -                        |
| -Methanol (GC)                                                                                                       | <= 200              | ppm  | 76                       |

Guido Colucci  
QC Manager  
Approved March 02, 2023

Agnese Messina  
Qualified Person  
Released March 03, 2023



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Product Code **C4050**  
Batch Number **2350000483**  
Batch Size **162,000 KG**

Manufacturing date **21/02/2023**  
Re-test date **26/01/2028**  
Certificate Nr. **040000064459**

| <u>Test</u>                                                                                                                                          | <u>Specification</u> | <u>M.U.</u> | <u>Result</u>            |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------|--------------------------|
| -Dimethylformamide (HPLC)                                                                                                                            | <= 100               | ppm         | < LOQ (5)                |
| ORGANIC IMPURITIES                                                                                                                                   | -                    | -           | -                        |
| 2-Acetylresorcinol (rel.sub. HPLC USP)                                                                                                               | <= 0,10              | %           | < Disregard limit (0,05) |
| Impurity A (rel. sub.HPLC USP)                                                                                                                       | <= 0,10              | %           | < Disregard limit (0,05) |
| Impurity B (rel. sub. HPLC USP)                                                                                                                      | <= 0,10              | %           | < Disregard limit (0,05) |
| Any other individual unspecified<br>impurity and Cromolyn tricarboxylic<br>acid analog (rel. sub. HPLC USP)                                          | <= 0,10              | %           | 0,05 (NOTE)              |
| Sum of all Impurities<br>(rel. sub. HPLC USP)                                                                                                        | <= 0,30              | %           | 0,05                     |
| ASSAY (HPLC)<br>(calculated on the anhydrous basis)                                                                                                  | 98,0 - 101,0         | %           | 100,2                    |
| ASSAY Ph.Eur. (pot.)<br>(anhydrous substances)                                                                                                       | 99,0 - 101,0         | %           | 100,1                    |
| ASSAY (JP)(pot.)(dried substance)                                                                                                                    | >= 98,0              | %           | 99,9                     |
| <b>NOTE</b><br><b>RRT 1,15 (EP)</b><br><b>NOTE</b><br><b>RRT 1,2 (EP)</b><br><b>NOTE</b><br><b>RRT 1,5 (EP)</b><br><b>NOTE</b><br><b>RRT(1,6)USP</b> |                      |             |                          |

**Solubility:** soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform.

**Complies with:** Ph.Eur. BP USP JP

**This material has been prepared following the current Good Manufacturing Practice (cGMP).**

|                                                        |                                                               |
|--------------------------------------------------------|---------------------------------------------------------------|
| Guido Colucci<br>QC Manager<br>Approved March 02, 2023 | Agnese Messina<br>Qualified Person<br>Released March 03, 2023 |
|--------------------------------------------------------|---------------------------------------------------------------|

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640  
Società Capogruppo P. & R. Principi Attivi S.p.A  
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**Modello:** C4050-STD / 4

March 03, 2023

This CoA is electronically dated and signed by authorized personnel of the Quality Unit

March 03, 2023

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