Olon Spa Stab. Casaletto Lodig
Via Livelli 1
26852 Fraz. Mairano (LO)

PEC: olon@pec.olonspa.it
Tel. HQ: +39 02 9523.1
Tel. Plant: +39 0371 739901

Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
20053 Rodano (MI)

METAPHARMACEUTICAL

N DE LOTE:
0120123

23/01/2023

# Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2250002654
Batch Size 192,000 KG

Manufacturing date 17/10/2022
Re-test date 11/10/2027
Certificate Nr. 040000059452

| Test | Specification | M.U. | Result |
|---|---|---|---|
| DESCRIPTION: white or almost white hygroscopic 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: a 2.0% solution in water is not more intensely coloured than reference solution BY5 | complies | | complies |
| CLARITY OF SOLUTION: a 2.0% solution in water is not more opalescent than reference suspension II | complies | | complies |
| COLOUR OF SOLUTION: Abs at 440 nm (5.0% solution) | <= 0,05 | AU | 0,01 |
| WATER | <= 10,0 | % | 7,6 |
| LOSS ON DRYING | <= 10,0 | % | 6,8 |
| 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 | % | 0,05 (NOTE) |
| Any other Impurity 1 (rel.sub. HPLC) | <= 0,10 | % | 0,03 (NOTE) |
| Any other Impurity 2 (rel.sub. HPLC) | <= 0,10 | % | 0,07 (NOTE) |
| Sum of all Impurities (rel.sub. HPLC) | <= 0,30 | % | 0,21 |
| -- | - | | - |
| RESIDUAL SOLVENTS: | - | | - |
| -Methanol (GC) | <= 200 | ppm | 70 |

Guido Colucci
QC Manager
Approved November 04, 2022

Agnese Messina
Qualified Person
Released November 07, 2022

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|---|---|---|---|
| -Dimethylformamide (HPLC) | <= 100 | ppm | 17 |
| -- | - | | - |
| 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 impurity and Cromolyn tricarboxylic acid analog (rel. sub. HPLC USP) | <= 0,10 | % | 0,06 (NOTE) |
| Sum of all Impurities (rel. sub. HPLC USP) | <= 0,30 | % | 0,06 |
| -- | - | | - |
| ASSAY (HPLC) (calculated on the anhydrous basis) | 98,0 - 101,0 | % | 99,6 |
| ASSAY Ph.Eur. (pot.) (anhydrous substances) | 99,0 - 101,0 | % | 100,5 |
| ASSAY (JP)(pot.)(dried substance) | >= 98,0 | % | 99,6 |
| **NOTE** | | | |
| **RRT 1,14 (EP)** | | | |
| **NOTE** | | | |
| **RRT 1,17 (EP)** | | | |
| **NOTE** | | | |
| **RRT 1,46 (EP)** | | | |
| **NOTE** | | | |
| **RRT(1,53)USP** | | | |

**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 November 04, 2022 | Agnese Messina<br>Qualified Person<br>Released November 07, 2022 |