Lote: 007/1/14

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Sifavitor™

Revision 4050-00



# SODIUM CROMOGLICATE

| | | | | | |
|---|---|---|---|---|---|
| **Batch N°:** | **4050/21/14** | **ANALYSIS CERTIFICATE N°** | **141941** | **Date:** | **30/10/2014** |
| Kg: | 197.00 | Formula: | $C_{23}H_{14}Na_2O_{11}$ | M.W.: | 512.3 |
| Man. date: | 08/10/2014 | Retest date: | Oct/2019 | Complies with: | Ph.Eur. BP USP JP |

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

| TESTS | SPECIFICATIONS | RESULTS |
|---|---|---|
| DESCRIPTION | white or almost white hygroscopic crystalline powder | complies |
| IDENTIFICATION | (1): IR spectrum<br>(2): UV spectrum<br>(3): sodium reaction | complies<br>complies<br>complies |
| ACIDITY OR ALKALINITY | (1): complies to Ph. Eur. test<br>(2): complies to USP test | complies<br>complies |
| APPEARANCE OF SOLUTION | a 2.0% solution in water is not more intensely coloured than *reference solution* $BY_5$ | complies |
| CLARITY OF SOLUTION | a 2.0% solution in water is not more opalescent than *reference suspension II* | complies |
| COLOUR OF SOLUTION | Abs at 440 nm not more than 0.05 (5.0% solution) | 0.01 |
| WATER | not more than 10.0% | 6.6% |
| LOSS ON DRYING | not more than 10.0% | 6.4% |
| OXALATE | not more than 0.35% | complies |
| HEAVY METALS | not more than 20 ppm | complies |

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

**Q.C. Manager** ..... 30/10/14 **Q.A. Manager** ..... 30/10/14 **Qualified Person** ..... 30/10/2014

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

| TESTS | SPECIFICATIONS | RESULTS |
|---|---|---|
| RELATED SUBSTANCES (TLC) | each impurity not more than 0.5% | no impurities detected |
| RELATED SUBSTANCES (HPLC) | (1): impurity 1 not more than 0.10% | < 0.01% |
| | (2): impurity 2 not more than 0.10% | < 0.01% |
| | (3): impurity 3 not more than 0.10% | < 0.01% |
| | (4): any other impurity not more than 0.10% | RRT 0.97: 0.02%<br>RRT 1.14: 0.05%<br>RRT 1.17: 0.01%<br>RRT 1.23: 0.02%<br>RRT 1.28: 0.01%<br>RRT 1.45: 0.01% |
| | (5): sum of all impurites not more than 0.30% | 0.12% |
| ASSAY | 99.0% to 101.0% with reference to the dried substance (pot.) | 99.2% |
| | 98.0% to 101.0% calculated on the anhydrous basis (UV) | 100.0% |
| RESIDUAL SOLVENTS | (1): methanol not more than 200 ppm (GC) | < LOQ |
| | (2): dimethylformamide not more than 100 ppm (HPLC) | < LOQ |

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Q.C. Manager ..... 30/10/14 Q.A. Manager ..... 30/10/14 Qualified Person ..... 30/10/2014

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