

|                                                                                                                                                                       |                                                                                                               |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--|
| <b>Sifavitor S.r.l.</b><br>Via Livelli 1 - 26952 Casaleto Lodigiano Fraz. Maltrano (LO) - ITALY<br>Tel: 0371-73991 - Fax 0371-73108 - e-mail: sifavitor@infagroup.com | <b>CERTIFICATE OF ANALYSIS</b><br>This batch has been produced following current good manufacturing practices |  |
|                                                                                                                                                                       |                                                                                                               |  |

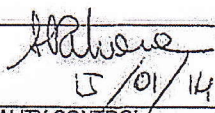
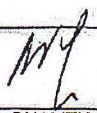
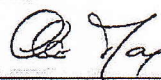
|                               |                   |                     |                                        |             |
|-------------------------------|-------------------|---------------------|----------------------------------------|-------------|
| <b>SODIUM CROMOGLICATE</b>    |                   |                     | Revision: 23/11/2012                   | Page 1 of 2 |
| Analysis Number 140005        | Batch: 4050/20/13 | Kg: 214.00          | Formula:                               | M.W:        |
| Analysis Date 14/01/2014      |                   |                     | $C_{23}H_{14}Na_2O_{11}$               | 512.34      |
| Manufacturing Date 30/11/2013 |                   | Retest Date 11/2018 | Complies with:<br>Ph.Eur.-BP-USP-JP-IP |             |

| TEST                                                  | RESULTS                          | SPECIFICATIONS                                                                                                                         |
|-------------------------------------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| DESCRIPTION<br>Aspetto                                | complies                         | White or almost white hygroscopic crystalline powder, odorless.                                                                        |
| IDENTIFICATION<br>Identificazione                     | complies<br>complies<br>complies | (1) IR spectrum<br>(2) UV spectrum<br>(3) reaction of sodium                                                                           |
| ACIDITY OR ALKALINITY<br>Acidità o alcalinità         | complies<br>complies             | (1) complies EP test<br>(2) complies USP test                                                                                          |
| APPEARANCE OF SOLUTION<br>Aspetto della soluzione     | complies                         | a 2% solution in water is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY5 |
| CLARITY OF SOLUTION<br>Limpidezza della soluzione     | complies                         | Not more opalescent than reference suspension II (2% solution)                                                                         |
| COLOUR OF SOLUTION<br>Colore della soluzione          | 0.02                             | Abs at 440 nm not more than 0.05 (5% solution)                                                                                         |
| WATER<br>Acqua                                        | 6.04%                            | Not more than 10.0%                                                                                                                    |
| LOSS ON DRYING<br>Perdita all'essiccamento            | 5.72%                            | Not more than 10.0%                                                                                                                    |
| OXALATE<br>Ossalati                                   | complies                         | Not more than 0.35%                                                                                                                    |
| HEAVY METALS<br>Metalli pesanti                       | complies                         | Not more than 20 ppm                                                                                                                   |
| RELATED SUBSTANCES (TLC)<br>Impurezze organiche (TLC) | no impurities detected           | Each impurity nmt 0.5%                                                                                                                 |

**Sifavitor S.r.l.**Via Livelli 1 - 26852 Casaleto Lodigiano Fraz. Mairano (LO) - ITALY  
Tel: 0371-73991 - Fax: 0371-73108 - e-mail: sifavitor@infagroup.com**CERTIFICATE OF ANALYSIS**

This batch has been produced following current good manufacturing practices

|                                                         |                                                                                                                                                                |                                                                                                                                                  |                                        |                |
|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|----------------|
| <b>SODIUM CROMOGLICATE</b>                              |                                                                                                                                                                |                                                                                                                                                  | Revision: 23/11/2012                   | Page 2 of 2    |
| Analysis Number 140005                                  | Batch: 4050/20/13                                                                                                                                              | Kg: 214.00                                                                                                                                       | Formula:<br>$C_{23}H_{14}Na_2O_{11}$   | M.W:<br>512.34 |
| Analysis Date 14/01/2014                                |                                                                                                                                                                |                                                                                                                                                  |                                        |                |
| Manufacturing Date 30/11/2013                           |                                                                                                                                                                | Retest Date 11/2018                                                                                                                              | Complies with:<br>Ph.Eur.-BP-USP-JP-IP |                |
| <b>TEST</b>                                             | <b>RESULTS</b>                                                                                                                                                 | <b>SPECIFICATIONS</b>                                                                                                                            |                                        |                |
| RELATED SUBSTANCES (HPLC)<br>Impurezze organiche (HPLC) | (1): < 0.01%<br>(2): < 0.01%<br>(3): < 0.01%<br>(4): RRT 0.97: 0.01%<br>RRT 1.14: 0.04%<br>RRT 1.17: 0.02%<br>RRT 1.23: 0.01%<br>RRT 1.45: 0.02%<br>(5): 0.10% | (1) imp.1 or DHA nmt 0.10%<br>(2) imp.2 or Cromo 01 nmt 0.10%<br>(3) imp.3 or diethylester der. nmt 0.10%<br>(4) Each unknown impurity nmt 0.10% |                                        |                |
|                                                         |                                                                                                                                                                | (5) Sum of all impurities nmt 0.30%                                                                                                              |                                        |                |
| ASSAY<br>Titolo                                         | A: 99.58%<br><br>B: 100.23%                                                                                                                                    | A: Btw 99.0% and 101.0% with reference to the dried substance (pot.)<br>B: Btw 98.0% and 101.0% calculated on the anhydrous basis (UV)           |                                        |                |
| RESIDUAL SOLVENTS<br>Solventi residui                   | methanol: 71 ppm<br>dimethylformamide: 8 ppm                                                                                                                   | A: methanol not more than 200 ppm (GC)<br>B: dimethylformamide not more than 100 ppm (HPLC)                                                      |                                        |                |

|                                                                                                 |                                                                                                 |                                                                                                     |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| <br>15/01/14 | <br>15/01/14 | <br>15/01/2014 |
| Issue: QUALITY CONTROL<br>Dr. Andrea Rebora                                                     | Control: QUALITY ASSURANCE<br>Dr. Attilio Virgili                                               | Approval: QUALIFIED PERSON<br>Dott.ssa Chiara Magnone                                               |