

No: Commer

## **Quality Control Laboratory**

| Certificate of Analysis                            |                           |   |                                     |
|--|---------------------------|---|-------------------------------------|
| Product: tri-Sodium Citrate Dihydrate USP43-BP2020 |                           |   |                                     |
| Batch No.:SCD01-102                                |                           |   |                                     |
| Quantity:2000 kg                                   |                           | Lab No.:QC146                               |                                     |
| Packing: 25 kg                                     |                           | Mfg. date: 28/01/01                         |                                     |
| Ref: BP2020-USP43                                  |                           | Exp. date: 28/01/04                         |                                     |
| No.  | Chemical Analysis         | Specifications                              | Results                             |
| 01   | Characteristics           | White or almost white, Crystalline          | Conforms                            |
|  |                           | Powder, Slightly deliquescent in moist air. |                                     |
| 02   | Identification A,B        | According to BP&USP requirements            | Passes the tests                    |
| 0.2  | G 1 1 1 1 1 .             | Freely soluble in water, practically        | <b>D</b> 41 4 4                     |
| 03   | Solubility                | insoluble in Ethanol(96 percent)            | Passes the tests                    |
| 04   | Appearance of solution    | Solution S is clear & colourless            | The solution was clear & colourless |
| 05   | Acidity or alkalinity     | According to BP&USP requirements            | The test sol. consumed 0.08 ml of   |
|  |                           |   | HCl 0.1 M                           |
| 06   | Readily carbonisable sub. | According to BP requirements                | Passes the test                     |
| 07   | Chlorides                 | Max. 50 ppm                                 | < 50 ppm                            |
| 08   | Oxalates                  | Max. 300 ppm                                | < 300 ppm                           |
| 09   | Sulfates                  | Max. 150 ppm                                | < 150 ppm                           |
| 10   | Water                     | 11 - 13 %                                   | 12.1 %                              |
| 11   | Tartrate                  | According to USP requirements               | Passes the test                     |
| 12   | Assay                     | 99.0 – 100.5 %                              | 99.4%                               |
| Date of Sampling:29/01/01                          |                           |   |                                     |
| Approved Rejected                                  |                           |   |                                     |
| Date of Analysis:30/01/01                          |                           |   |                                     |
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| Analyst Q.C.Manager Authorized by:                 |                           |   |                                     |
| Analyst Q.C.Manager Authorize                      |                           |   | manel Authorized by:                |
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|  |                           |   |                                     |

We hereby certify that this product has been prepared under GMP regulation and tested according & conform to the requirements of USP43- BP2020. The raw materials, manufacturing process and product do not contain any of the solvents listed in organic volatile impurities (USP<467>) and residual solvents BP<5.4>