



## CERTIFICATE OF ANALYSIS

| Product Name: Microcrystalline Cellulose PH 102 (BP/USP) |  | A.R. No.: 1085   |           |
|--|--|--|-----------|
| Batch No.: 1085  |  |  |           |
| Mfg .Date : 12/2024                                      |  | Exp. Date : 11/2029  |           |
| Batch Size : 6000 Kg                                     |  | Date of analysis: 02/12/2024   |           |
| Sr. No   | Test   | Specification  | Results   |
| 01   | Description  | White or almost white, fine or granular, slightly hygroscopic powder. (BP)   | Complies  |
|  |  | Fine, White or almost white powder. It consists of free-flowing, nonfibrous particles. (USP)   | Complies  |
| 02   | Solubility   | Practically insoluble in water, in acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/l solution of sodium hydroxide. (BP) | Complies  |
|  |  | Practically insoluble in sodium hydroxide solution (1 in 20), insoluble in water, in dilute acids, and in most organic solvent. (USP)            | Complies  |
|  |  | (In copper tetramine solution) Dissolve completely, leaving no residue. (BP)   | Complies  |
| 03   | Identification   |  |           |
|  | Test A: (Infrared (IR) absorption)                                 | Disregard any band between 800 cm <sup>-1</sup> and 825 cm <sup>-1</sup> or between 950 cm <sup>-1</sup> and 1000 cm <sup>-1</sup>               | Complies  |
|  | Test B: (Iodinated Zinc chloride test)                             | The substance becomes violet-blue  | Complies  |
|  | Test C: (Degree of polymerization)                                 | NMT 350  | 280       |
| 04   | Sulfated Ash/Residue on ignition                                   | NMT 0.1 %  | 0.035 %   |
| 05   | Conductivity (In supernatant)                                      | NMT 75µS per cm  | 45 µS/cm  |
| 06   | pH (In supernatant)  | 5.0 to 7.5   | 6.30      |
| 07   | Loss on Drying   | NMT 7.0 %  | 5.45 %    |
| 08   | Bulk density   | 0.26 g/ml to 0.36 g/ml   | 0.35 g/ml |
| 09   | Arsenic  | NMT 2 ppm  | Complies  |
| 10   | Heavy Metals   | NMT 10 ppm   | Complies  |
| 11   | Water soluble substances   | NMT 0.25%  | 0.15 %    |
| 12   | Ether-soluble substances   | NMT 0.05 %   | 0.030     |
| 13   | Particle Size distribution   |  |           |
|  | Retained (+) 60 mesh   | NMT 8.0 % m/m  | 4 %       |
|  | Retained (+) 200 mesh  | NLT 45.0 % m/m   | 56 %      |
| 14   | Microbial enumeration tests and tests for specified microorganisms |  |           |
|  | a. Total aerobic microbial count                                   | NMT 1000 cfu per gm.   | Complies  |
|  | b. Total molds and yeasts count                                    | NMT 100 cfu per gm.  | Complies  |
|  | c. Staphylococcus aureus   | Must be absent   | Absent    |
|  | d. Pseudomonas aeruginosa  | Must be absent   | Absent    |
|  | e. Escherichia coli  | Must be absent   | Absent    |
|  | f. Salmonella species.   | Must be absent   | Absent    |

## REMARKS:

The sample of above product complies with the latest monograph of BP/USP-47.

1. No solvent is used in manufacturing process of microcrystalline cellulose PH-102.
2. Abbreviation: - NMT- Not more than, NLT- Not less than.