

## SPECIFICATION

|                                                               |
|---------------------------------------------------------------|
| <b>Product Name:</b> Microcrystalline Cellulose- 101 IP Grade |
| <b>Chemical Formula:</b> $(C_6H_{10}O_5)_n$                   |
| <b>CAS Number:</b> 9004-34-6                                  |
| <b>Molecular Weight:</b> 36000 g/mol                          |
| <b>Appearance:</b> White or almost white fine powder          |
| <b>Odor:</b> Odorless                                         |

### Chemical Composition

| Parameter                                                    | Unit | Typical Value | Specification (Min./Max.)                                                                       |
|--------------------------------------------------------------|------|---------------|-------------------------------------------------------------------------------------------------|
| <b>Identification</b>                                        |      |               |                                                                                                 |
| Test - (A) By IR                                             | -    | Complies      | A red colour is produced                                                                        |
| Test- (B) By Chemical                                        | -    | Complies      | A blue- purple colour is produced                                                               |
| Test- (C) Dispersion test                                    | -    | Complies      | A white, opaque, bubble free dispersion is obtained that does not produce a supernatant liquid. |
| pH of solution (5.0 g with 40 ml CO <sub>2</sub> free water) | -    | 6.00          | 5.0 to 7.5                                                                                      |
| Starch and dextrin                                           | -    | Complies      | No blue or brownish red colour is produced.                                                     |
| Organic Impurities                                           | -    | Complies      | No red colour is produced                                                                       |
| Water- soluble substances                                    | %    | 0.14%         | Max. 0.20%                                                                                      |
| Arsenic                                                      | PPM  | Complies      | NMT 2 PPM                                                                                       |
| Heavy metals                                                 | PPM  | Complies      | Max. 10 PPM                                                                                     |
| Loss on drying (at 105°C for 3h)                             | %    | 3.20%         | Max. 6.0%                                                                                       |
| Sulphated ash (calculated on dried basis)                    | %    | 0.06%         | Max. 0.10%                                                                                      |

### **Physical Properties**

- Solubility: Insoluble in water. Insoluble in ethanol. Insoluble in ether. Insoluble in acetone. Insoluble in dilute acids and alkalis.

### **Shelf Life & Storage**

- Shelf Life: 5 years from date of manufacture under recommended storage.  
- Storage Conditions: Store in a cool, dry place at 15–30°C. Protect from moisture, excessive humidity, and contamination. Keep the container tightly closed in the original, properly labeled container and store in a well-ventilated area away from direct sunlight to maintain product quality, flow properties, and stability.

### **Applications**

- Use: Widely used as a pharmaceutical excipient in the manufacture of tablets, capsules, sachets, and dry powder formulations. It functions as a diluent (filler), dry binder, disintegrant, and flow aid, improving powder flow, compressibility, tablet hardness, content uniformity, and disintegration.  
- Dosage: Depends on the intended formulation, dosage form, manufacturing process, and the properties of the active pharmaceutical ingredient (API).

### **Packaging**

- Standard Packing: 25 Kgs woven pp bag with inner liner or as per customer requirement.  
- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.  
\* Specifications are based on the manufacturer's provided specifications.