

TECHNICAL SPECIFICATION

| PRODUCT NAME | | BOTANICAL NAME | PLANT PART USED |
|----------------------------|-------------------|--------------------------|-----------------|
| BERBERINE HCL 97% GRANULES | | <i>Berberis Aristata</i> | Roots |
| PRODUCT CODE | EXTRACTION METHOD | ORIGIN COUNTRY | HERB RATIO |
| BCE97BG | Water | India | 55:1 |
| DOC No. & REV No. | SUPERCEDES | EFFECTIVE DATE | REVIEW DATE |
| FSSC/8.5/F8/BCE002-00 | NIL | 01.04.2023 | 31.03.2026 |

| S. No. | PARAMETER | SPECIFICATION | TEST METHOD |
|----------|-------------------------|---|--------------|
| A | PHYSICAL | | |
| A1 | Description | Yellow Granules having characteristic odour & taste | Organoleptic |
| A2 | Identification | Positive | USP |
| A3 | Particle Size | NLT 95% through 20# NMT 15% through 60# | USP <786> |
| A4 | Loose Bulk Density | 0.30 gm/ml - 0.50 gm/ml | USP <616> |
| A5 | Tapped Density | 0.40 gm/ml - 0.80 gm/ml | USP <616> |
| B | CHEMICAL | | |
| B1 | Berberine HCL | NLT 97% On Dry Basis | HPLC |
| B2 | Loss on Drying | NMT 12% | USP <731> |
| B3 | pH | 03 - 07 | USP <791> |
| B4 | Excipients | None | In House |
| B5 | Solubility in Water | Partially Soluble | In House |
| C | RESIDUAL SOLVENT | | |
| C1 | Residual Solvents | 100% Solvent Free | USP <467> |
| D | HEAVY METALS | | |
| D1 | Lead | NMT 3 ppm | USP <2232> |
| D2 | Mercury | NMT 0.1ppm | USP <2232> |
| D3 | Arsenic | NMT 1 ppm | USP <2232> |
| D4 | Cadmium | NMT 1 ppm | USP <2232> |
| E | MICROBIOLOGY | | |
| E1 | Total Plate Count | NMT 5000 cfu/gm | USP <2021> |
| E2 | Enterobacterial Count | NMT 100 cfu/gm | USP <2021> |
| E3 | Yeast & Mould | NMT 100 cfu/gm | USP <2021> |
| E4 | Coliforms | NMT 10 cfu/gm | BAM 2001 |
| E5 | Escherichia Coli | Absent/10gm | USP <2022> |
| E6 | Salmonella | Absent/10gm | USP <2022> |
| E7 | Staphylococcus aureus | Absent/10gm | USP <2022> |
| F | PESTICIDES | | |
| F1 | Pesticides | Complies as per USP | USP <561> |
| G | OTHER DETAILS | | |
| G1 | Packaging Details | Net 25kg in double-lined food-grade LLDPE polybag packed in a HDPE drum. | |
| G2 | Shelf Life | 36 months from year of manufacturing. | |
| G3 | Storage | Store in dry & air tight containers, away from sunlight, at room temperature. | |
| G4 | Note | There might be minor colour variation on account of seasonal variation of the raw material. Colour variation does not impact the efficacy and quality of the product. | |