

## TECHNICAL SPECIFICATION

PRODUCT NAME		BOTANICAL NAME	PLANT PART USED
BERBERINE HCL 97% POWDER		<i>Berberis Aristata</i>	Roots
PRODUCT CODE	EXTRACTION METHOD	ORIGIN COUNTRY	HERB RATIO
BCE97BH	Aqueous	India	55:1
DOC No. & REV No.	SUPERCEDES	EFFECTIVE DATE	REVIEW DATE
FSSC/8.5/F8/BCE001-00	NIL	01.04.2023	31.03.2026

S. No.	PARAMETER	SPECIFICATION	TEST METHOD
<b>A</b>	<b>PHYSICAL</b>		
A1	Description	Yellow Powder having characteristic odour & taste	Organoleptic
A2	Identification	Positive	USP
A3	Particle Size	NLT 95% through 40#	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>B</b>	<b>CHEMICAL</b>		
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
<b>C</b>	<b>RESIDUAL SOLVENT</b>		
C1	Residual Solvents	100% Solvent Free	USP <467>
<b>D</b>	<b>HEAVY METALS</b>		
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>
<b>E</b>	<b>MICROBIOLOGY</b>		
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>
<b>F</b>	<b>PESTICIDES</b>		
F1	Pesticides	Complies as per USP	USP <561>
<b>G</b>	<b>OTHER DETAILS</b>		
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.	