

CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd., manufacturer and supplier of quality chemicals.

Product Name	Berberine HCl
C.A.S. Number	633-65-8
Molecular Formula	—
Molecular Weight	—
Grade / Standard	97% HPLC
Physical Form	Yellow crystalline powder
Product Category	Nutraceuticals & Herbal Extracts
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	Yellow crystalline powder	Complies	Visual
2	Identification	Conforms to the structure of the substance	Complies	FTIR / Chemical test
3	Solubility	As per specification	Complies	Visual / Monograph
4	Assay	Not less than 97.0 % w/w	97.35	Titrimetry / Instrumental
5	Loss on Drying	Not more than 5.0 % w/w	2.94	Gravimetry
6	Total Ash	Not more than 5.0 % w/w	3.08	Gravimetry
7	Bulk Density	As per specification	0.53 g/mL	Tapped density
8	Particle Size — through 80 mesh	Not less than 95 %	98.8	Sieve analysis
9	Pesticide Residues	Complies with USP <561>	Complies	GC-MS / LC-MS
10	Aflatoxins (B1, B2, G1, G2)	Not more than 20 ppb	Less than 2 ppb	HPLC-FLD
11	Residual Solvents	Complies with ICH Q3C	Complies	Headspace GC
12	Lead (Pb)	Not more than 3.0 ppm	Less than 0.5 ppm	ICP-MS
13	Heavy Metals (as Pb)	Not more than 10 ppm	Less than 5 ppm	ICP-OES
14	Total Aerobic Microbial Count	Not more than 1000 cfu/g	102 cfu/g	IP / USP <61>
15	Total Yeast & Mould Count	Not more than 100 cfu/g	9 cfu/g	IP / USP <61>
16	Escherichia coli	Absent in 1 g	Absent	IP / USP <62>
17	Salmonella species	Absent in 10 g	Absent	IP / USP <62>
18	Structure	Conforms to reference structure	Complies	FTIR / NMR

Remarks

Material supplied against this specification is analysed on every production lot and **conforms** to the limits stated above in all tested parameters. Results shown are the typical values obtained for this grade.

Retained samples are held against every export consignment. Store in tightly closed original packing, in a cool, dry, well-ventilated place away from incompatible materials and direct sunlight.

Checked and Approved by**Prem Panchal**

Quality Assurance
Scapex Exports Pvt. Ltd.

This document sets out the standard specification for the product named above and applies to all consignments of this grade. It is issued by Scapex Exports Pvt. Ltd. as manufacturer and supplier. Refer to the Material Safety Data Sheet (MSDS) before handling.