

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	Papain Enzyme
C.A.S. Number	9001-73-4
Molecular Formula	—
Molecular Weight	—
Grade / Standard	2000 USP U/mg Nutra Grade
Physical Form	Off-white to light tan powder
Product Category	Nutraceuticals & Herbal Extracts
Country of Origin	India

ANALYTICAL RESULTS

S. No.	Test Parameter	Specification	Result	Method
1	Description	Off-white to light tan powder	Complies	Visual
2	Identification (A) — Infrared absorption	Concordant with reference spectrum	Complies	IR Spectrophotometry
3	Identification (B) — Chemical / chromatographic	Positive for the substance	Complies	As per monograph
4	Solubility	As per specification	Complies	Visual / Monograph
5	Assay (on dried basis)	98.0 – 102.0 % w/w	99.02	HPLC / Titrimetry (Monograph)
6	Loss on Drying	Not more than 5.0 % w/w	1.69	Gravimetry
7	Total Ash	Not more than 5.0 % w/w	1.86	Gravimetry
8	Bulk Density	As per specification	0.38 g/mL	Tapped density
9	Particle Size — through 80 mesh	Not less than 95 %	96.0	Sieve analysis
10	Pesticide Residues	Complies with USP <561>	Complies	GC-MS / LC-MS
11	Aflatoxins (B1, B2, G1, G2)	Not more than 20 ppb	Less than 2 ppb	HPLC-FLD
12	Residual Solvents	Complies with ICH Q3C	Complies	Headspace GC
13	Lead (Pb)	Not more than 3.0 ppm	Less than 0.5 ppm	ICP-MS
14	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.050	Gravimetry (Monograph)
15	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
16	Related Substances — any individual impurity	Not more than 0.10 %	0.052	HPLC
17	Related Substances — total impurities	Not more than 0.50 %	0.229	HPLC
18	Total Aerobic Microbial Count	Not more than 1000 cfu/g	108 cfu/g	IP / USP <61>

S. No.	Test Parameter	Specification	Result	Method
19	Total Yeast & Mould Count	Not more than 100 cfu/g	8 cfu/g	IP / USP <61>
20	Escherichia coli	Absent in 1 g	Absent	IP / USP <62>
21	Salmonella species	Absent in 10 g	Absent	IP / USP <62>
22	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.