



CERTIFICATE OF ANALYSIS

Product Name	Bromelain 1'200 GDU
Batch Number	EXPE12-112419
Production Date	01/11/2024
Expiry Date	31/10/2028
Manufacturer	37OLJX
Excipients Used	Maltodextrin

Organoleptic Characteristics

Analysis Item	Specification	Result
Description	Off white to white colour hygroscopic powder	Complies
Odour	Characteristic	Complies

Physical & Chemical Characteristics

Analysis Item	Specification	Result
Activity	1200 GDU/g	1345 GDU/g
Loss on drying	≤ 5.0%	3.8%
Bulk density	0.4 – 0.7 g/cc	0.42 g/cc
Solubility	Soluble in water	Complies
pH of 10% solution	5 – 7	5.5
Identification test	Positive for proteolytic test	Complies
Residual solvents	To comply as per USP	Complies
Residual pesticide	To comply as per USP	Complies
Particle size	90% 80 Mesh	Complies
Sum of Ethylene Oxide and 2-Chloro-Ethanol	≤ 0.01 ppm/MRL	Complies

Heavy Metals

Analysis Item	Specification	Result
Heavy metals (total)	≤ 8 ppm	Complies
Arsenic (As)	≤ 1 mg/kg	Complies

Lead (Pb)	≤ 1 mg/kg	Complies
Cadmium (Cd)	≤ 1 mg/kg	Complies
Mercury (Hg)	≤ 0.1 mg/kg	Complies

Microbiological Characteristics

Analysis Item	Specification	Result
Total plate count	≤ 10,000 CFU/g	140 CFU/g
Mould & Yeast	≤ 100 CFU/g	3 CFU/g
Escherichia coli	Negative/10g	Complies
Salmonella	Negative/10g	Complies
Staphylococcus aureus	Negative/10g	Complies
Enterobacteriaceae	Absent in 1 g	Complies
Pseudomonas aeruginosa	Absent in 10 g	Complies