

BaseBulk

CERTIFICATE OF ANALYSIS

Product Name	DigeZyme®
Product Code	0535
Batch No.	G240594
TR No.	80000008707
Date of Manufacture	December 2024
Date of Expiry	November 2028

Physical & Chemical Characteristics

Analysis Item	Specification	Result
Description	Off white to creamy white powder with characteristic odour	Complies
Solubility	Slightly soluble in water, insoluble in ethanol, acetone and isopropyl alcohol	Complies
Water activity	NMT 0.6	0.223
Ash content	NMT 10.0% w/w	0.20 % w/w
Sieve Test (passes through: 40 mesh)	NLT 95% w/w	99.77 % w/w

Enzymatic Activity

Analysis Item	Specification	Result
Amylolytic activity – alpha amylase	NLT 24000 DU/g	29340 DU/g
Proteolytic activity – neutral protease	NLT 6000 PC/g	7860 PC/G
Cellulolytic activity – cellulase	NLT 1100 CU/g	1420 CU/G
Lactase	NLT 4000 ALU/g	5400 ALU/G
Lipolytic activity – lipase	NLT 200 FIP/g	260 FIP/G

Heavy Metals

Analysis Item	Specification	Result
Lead	NMT 3 ppm ($\mu\text{g/g}$)	<0.20 ppm ($\mu\text{g/g}$)
Arsenic	NMT 1 ppm ($\mu\text{g/g}$)	<0.20 ppm ($\mu\text{g/g}$)
Cadmium	NMT 1 ppm ($\mu\text{g/g}$)	<0.20 ppm ($\mu\text{g/g}$)
Mercury	NMT 0.1 ppm ($\mu\text{g/g}$)	<0.02 ppm ($\mu\text{g/g}$)

Residual Solvents

Analysis Item	Specification	Result
Residual Solvents: Ethylene oxide + 2-Chloroethanol	NMT 10 ppb ($\mu\text{g/kg}$)	Complies

Contaminants

Analysis Item	Specification	Result
Chloramphenicol (MRPL) by LC-MS/MS	NMT 0.3 ppb ($\mu\text{g/kg}$)	Complies

Microbiological Tests

Analysis Item	Specification	Result
Total aerobic microbial count	NMT 5000 cfu/g	975 cfu/g
Total yeasts and molds count	NMT 100 cfu/g	<10 cfu/g
Escherichia coli	Negative/10 g	Complies
Salmonella	Negative/10 g	Complies
Staphylococcus aureus	Negative/10 g	Complies
Pseudomonas aeruginosa	Negative/10 g	Complies
Bile tolerant gram negative bacteria	NMT 100 cfu/g	<10 cfu/g
Coliforms	Less than 10 cfu/g	<10 cfu/g

General Status

Category	Intended for Nutraceutical application
Preparation type	Multienzyme complex
Standardization	Enzymatic activity
Excipient used	Maltodextrin 70% to 78% (CAS 9050-36-6)

Sanitising treatment	Non-irradiated and not treated with ETO
Certification Status	Kosher and Halal certified
BSE/TSE status	BSE / TSE free
Genetic Modification Status	Non-GMO
Country of Origin	India

Base Bulk