

CERTIFICATE OF ANALYSIS

Product Name	: DIGEZYME FJ		
Product Code	: 0535FJ		
Batch No.	: G210435	Date of Manufacture	: Sep/2021
T R No.	: NL21F0226	Date of Expiry	: Aug/2024
Category	: Intended for Nutraceutical application		
Preparation type	: Multienzyme complex		
Standardization	: Enzymatic activity		
Excipients used	: Maltodextrin		
Excipients Details	Name	Used %	CAS No.
	Maltodextrin	63% to 71%	9050-36-6
Parameter	Result	Limit	Reference
Physical			
Description	Complies	Off white to creamy white powder with characteristic odour	Visual and Organoleptic
Taste	Complies	Slightly sweet to sweet or slightly salty taste	Organoleptic
Solubility	Complies	Slightly soluble in water, insoluble in ethanol, acetone and isopropyl alcohol	USP
Loss on drying	4.42 % w/w	Not more than 5.0% w/w (dried at 105°C)	USP <731>
Ash content	1.42 % w/w	Not more than 3.0% w/w	USP <561>
<i>Sieve Test (Passes through)</i>			USP <786>
- 40 mesh	99.49 % w/w	Not less than 95% w/w	
Biochemical			
-Amylolytic activity - alpha amylase	30230.00 U/g	Not less than 24000 U/g (24000 DU/g) (Dextrinizing Unit / gram)	SLL/STP-A-029
-Proteolytic activity - neutral protease	7780.00 U/g	Not less than 6000 U/g (6000 PC/g) (Protease Unit on L-tyrosine basis / gram)	SLL/STP-P-021
-Cellulolytic activity - cellulase	380.00 U/g	Not less than 200 U/g (1100 CU/g) (Cellulase Unit / gram)	SLL/STP-C-021
-Beta-D-Galactosidase galactohydrolase lactase	5675.00 U/g	Not less than 4000 U/g (4000 ALU/g) (Acid Lactase Unit / gram)	SLL/STP-L-014
-Lipolytic activity lipase	1310.00 U/g	Not less than 1000 U/g (200 FIP/g) (Fungal Lipase International Unit / gram)	SLL/STP-L-016
Others			
Lead	<0.2 ppm (µg/g)	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	<0.2 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	<0.2 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Mercury	<0.02 ppm (µg/g)	Not more than 0.1ppm (µg/g)	USP <2232>
Sodium	0.01 % w/w	Not more than 0.5% w/w	SLL/STP-S-029

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Parameter	Result	Limit	
Microbiological Profile			
Total aerobic microbial count	100 cfu/g	Not more than 3000cfu/g	USP <2021>
Total yeasts and molds count	<10 cfu/g	Not more than 100cfu/g	USP <2021>
Escherichia coli	Complies	Negative/10g	USP <2022>
Salmonella	Complies	Negative/10g	USP <2022>
Staphylococcus aureus	Complies	Negative/10g	USP <2022>
Pseudomonas aeruginosa	Complies	Negative/10g	USP <62>
Bile tolerant gram negative bacteria	<10 cfu/g	Not more than 100cfu/g	USP <2021>
Coliforms	Complies	Negative/10g	BAM 2001, 8th Edition, Chapter 4

Additional Information	
Sanitising treatment	Non-irradiated and not treated with ETO
Certification Status (Kosher/Halal)	Kosher and Halal certified
Genetic Modification Status	Non-GMO Project Verified
BSE/TSE status	BSE / TSE free
Country of Origin	India
Storage condition	Store at room temperature

Manufactured by	SAMI-SABINSA GROUP LIMITED, 19/1 & 19/2, I Main, II Phase, Peenya Industrial Area, Bangalore - 560058, Karnataka, India
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Note: Gluten Free

Remarks : The product complies as per the specification No. FPS/ARD/149, Issue No. 10 Dated: June 17, 2021

Disclaimer: Suitability of this product for its particular use is at the sole discretion of the purchaser.

For Sabinsa Korea Corporation

Date: 07-Oct-2021

****In-House developed and validated methods**