



SABINSA EUROPE GMBH
 *Pharmaceuticals *Phytochemicals
 *Fine Chemicals *Herbal Extracts
 *Cosmeceuticals *Specialty Chemicals
CERTIFICATE OF ANALYSIS

Product Name DigeZyme®
Product Code 0535
Batch No. G220281
TR No. NL22F0188
Date of Manufacture May 2022
Date of Expiry April 2025



Sold To : BECARRE NATURAL
PO No. : PCA23000115

Quantity : 25.00 Kg

Category Intended for Nutraceutical application
Preparation type Multienzyme complex
Standardization Enzymatic activity
Excipient Used Maltodextrin

Excipient name	%Used	CAS No.
Maltodextrin	70% to 78%	9050-36-6

Parameters
PHYSICAL

Result	Limit	Reference
Complies	Off white to creamy white powder with characteristic odour	Visual and Organoleptic
Complies	Slightly soluble in water, insoluble in ethanol, acetone and isopropyl alcohol	USP
4.23 % w/w	Not more than 5.0% w/w (dried at 105°C)	EP 2.2.32
0.33 % w/w	Not more than 10.0% w/w	EP 2.4.14
99.69 % w/w	Not less than 95% w/w	USP <786>

CHEMICAL

Biochemical

-Amylolytic activity - alpha amylase	30470.00 DU/g	Not less than 24000 DU/g (Dextrinizing Unit / gram)	SLL/STP-A-029
-Proteolytic activity - neutral protease	7540.00 PC/G	Not less than 6000 PC/g (Protease Unit on L-tyrosine basis / gram)	SLL/STP-P-021
-Cellulolytic activity - cellulase	1340.00 CU/G	Not less than 1100 CU/g (Cellulase Unit / gram)	SLL/STP-C-021



Product Name DigeZyme®
Product Code 0535
Batch No. G220281
TR No. NL22F0188
Date of Manufacture May 2022
Date of Expiry April 2025



-Beta-D-Galactosidase galactohydrolase lactase	5490.00 ALU/G	Not less than 4000 ALU/g (Acid Lactase Unit / gram)	SLL/STP-L-014
-Lipolytic activity - lipase	255.00 FIP/G	Not less than 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>
Chloramphenicol {Minimum required performance limit (MRPL)} by LC MS/MS	Complies	Not more than 0.3ppb (µg/kg)	SLL/STP-C-060

MICROBIOLOGICAL PROFILE

Total aerobic microbial count	1500 cfu/g	Not more than 5000cfu/g	EP 2.6.12
Total yeasts and molds count	<10 cfu/g	Not more than 100cfu/g	EP 2.6.12
Escherichia coli	Complies	Negative/10g	EP 2.6.13
Salmonella	Complies	Negative/10g	EP 2.6.13
Staphylococcus aureus	Complies	Negative/10g	EP 2.6.13
Pseudomonas aeruginosa	Complies	Negative/10g	EP 2.6.13
Bile tolerant gram negative bacteria	<10 cfu/g	Not more than 100cfu/g	EP 2.6.13
Coliforms	<10 cfu/g	Less than 10 cfu/g	

ADDITIONAL INFORMATION

Sanitising treatment Non-irradiated and not treated with ETO
 Certification Status (Kosher/Halal) Kosher certified, Halal certified



SABINSA EUROPE GmbH
 *Pharmaceuticals *Phytochemicals
 *Fine Chemicals *Herbal Extracts
 *Cosmeceuticals *Specialty Chemicals
CERTIFICATE OF ANALYSIS

Product Name DigeZyme®
Product Code 0535
Batch No. G220281
TR No. NL22F0188
Date of Manufacture May 2022
Date of Expiry April 2025



Genetic Modification Status Non-GMO Project Verified
BSE/TSE status BSE / TSE free
Storage condition Store at room temperature
Country of Origin India
Manufactured By Sami-Sabinsa Group Limited
 19/1,19/2 I Main, II Phase,Peenya Industrial Area,Bangalore - 560058, Karnataka, India
Manufactured At Sami-Sabinsa Group Limited - Nelamangala
 No. 19/3, 20/1 & 20/2/2, Bhavikere Village, Kasaba Hobli,Nelamangala - 562123
Remarks Note: Gluten Free

The above certificate of analysis is based on **Specifications Issue No: 8 Dated: August 18, 2020**

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

NAP:Not Applicable

NAV:Not Available