Safepure

Arjuna Natural

CERTIFICATE OF ANALYSIS
HERBAGUT®

Product name	:	Herbagut®	AN Code	:	507102011
Quantity	:		Old Product code	:	CCHE- 014 PLUS
Country of Origin	:	India	Batch no	:	1F5072402001
COA No.	:	EB240600146	Manu. Date	:	22.02.2024
COA Date	:	12.06.2024	Expiry Date	:	21.02.2027

Description	Specification	Result	Method
Description: Proprietary blend of 14 unique ingredients			
Physical Characteristic			
Identification	Pass	Complies	TLC
Colour	Yellowish brown	Complies	Visual
Appearance	Powder	Complies	Visual
Flavour	Bitter and spicy flavour characteristic of herbs	Complies	Organoleptic
Odour	Characteristic	Complies	Organoleptic
Analytical Assay			
Solubility (in Alcohol	NLT 40%	Complies	IP
Extraction solvent	Hydro- alcohol (70:30) Ethyl Acetate *	Complies	In House Specification
Residual solvent	NMT 5000 ppm	Complies	USP<467>
Moisture	NMT 6%	3.90%	USP 37 <921>
Tap Density (Gm/ml)	> 0.60	0.65	USP 37 <616>
Bulk Density (Gm/ml)	> 0.30	0.38	USP 37 <616>
Particle Size	100% thru 30 #	Complies	USP 37 <786>
Excepients	Cellulose	Complies	In House Specification
Microbial Assay			
Total Plate Count	NMT10,000 cfu/g	10 cfu/g	AOAC, BAM
Yeast & Mould	NMT1000 cfu/g	Not Detected	AOAC, BAM
Salmonella	Absent/25 g	Absent/25 g	AOAC, BAM
E. coli	Absent/10 g	Absent/10 g	AOAC, BAM
Coliforms	Absent /10 g	Absent/10 g	AOAC, BAM
Assay			
Total polyphenol	NLT 15%	16.80%	Spectrophotometer
Total Curcuminoids	NLT 6%	6.49%	HPLC

Arjuna Natural Pvt. Ltd.
PB. No. 126, Bank Road
Aluva - 683101, Kerala, India.

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CIN. U24239KL1992PTC006670

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Description	Specification	Result	Method
Contaminants			
Total heavy metals	NMT 10 ppm	Complies	ICP-MS
Lead	NMT 3 ppm	Complies	ICP-MS
Arsenic	NMT 1 ppm	Complies	ICP-MS
Mercury	NMT 0.1 ppm	Complies	ICP-MS
Cadmium	NMT 1 ppm	Complies	ICP-MS
Benzo(a)pyrene	<10 µg/kg	Complies	UPLC-Fluro
Polycyclic aromatic hydrocarbon	<50µg/kg	Complies	UPLC-Fluro
(sum of Benzo(a)pyrene, Benzo(a) anthracene. Benzo(b)fluoranthene, chrysene)			
Pesticide Residue	Complies with EU	Complies	USP 37<561>
Aflatoxin	Complies with EU	Complies	UPLC- Fluro

Ingredients

1.	Murraya koenigii	2.	Terminallia bellerica
3.	Glycyrrhiza glabra	4.	Momordica charantia
5.	Piper nigrum	6.	Piper longum
7.	Cyperus rotundus	8.	Asparagus racemosus
9.	Alpinia galanga	10.	Terminalia chebula
11.	Centella asiatica	12.	Curcuma longa
13.	Andrographis paniculata	14.	Zingiber officinale

* Ethyl acetate is used for the extraction of *Curcuma longa & Zingiber officinale*

	Prepared by	Approved by
Signature		
Name	Balakrishna Shenoi B	Krishnaveni M S
Designation	Asst. Manager - QC	Head - QC

Additional Product information

- Material is Non-ETO, Non-Irradiated, GMO-Free and BSE-TSE free
- Allergens: No Allergens
- Storage: Store in a cool, dry place and away from direct sunlight
- Kosher Certified
- Shelf life is 24 months from the date of manufacturing
- Packaging details: 25Kg HMHDPE drums

Note: Since it is a herbal product, there is likely to be minor colour variation from batch to batch because of the seasonal variations of the raw materials. Colour change will not affect the quality and efficacy of the product

Old Product code will be valid till 01.04.2027 and further this date it will be replaced by AN Code

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STATEMENTS
HERBAGUT (CCHE-014 PLUS)

BSE-TSE
This product is BSE/TSE free according regulation (CE) 220/2009

GENETICALLY MODIFIED ORGANISMS – GMO
This product is free from Genetically Modified Organisms. This ingredient is compliant in all respects with the Regulations N°1829/2003/EC and N°1830/2003/EC where applicable

ALLERGENS
This ingredient does not contain substances or products causing allergies or intolerances according Regulation (EU) N° 1169/2011

PRODUCT SOURCE
This ingredient is manufactured from herbal material, so has vegetable origin. No animal containing ingredients are used in any part of the manufacturing process according Regulation (EC)No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

VEGETARIANS/VEGANS:
This product is suitable for Vegetarians, because: "it is free of all animals and fish products and derivatives thereof, except maybe for honey, egg, milk and milk products". It is also suitable for Vegans, because: "no products are issued from animals, including honey, egg, milk, and milk products".

ANIMAL TESTING
This product has not been the subject of animal testing according EU Cosmetic Regulation (EC/1223/2009) . Known toxicity studies on animals might have been carried out by others before Regulation EC/1223/2009 came into action or outside the region of this Regulation's influence

HAZARDS IDENTIFICATION
• Classification of the substance or mixture
Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008
This substance is not classified as dangerous according to Directive 67/548/EEC.

• Label elements
The product does not need to be labelled in accordance with Regulation (EC) No 1272/2008 [CLP].

IMPORT & EXPORT
This substance is not listed in the Annex I of Dangerous Chemicals (Regulation (EC) No 649/2012).

RISK ASSESMENT
This substance is not listed in a priority list (as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances.).

DOPING LIST
This product does not contain, nor is it contaminated with substances on the current World Anti-Doping Agency (WADA) Prohibited substances list

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CERTIFICATE OF ANALYSIS

Product Name	**DigeZyme®**
Product Code	**0535**
Batch No.	**G230667**
TR No.	**40000010354**
Date of Manufacture	**December 2023**
Date of Expiry	**November 2026**

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	**Result**	**Limit**	**Reference**
PHYSICAL			
Description	Complies	Off white to creamy white powder with characteristic odour	Visual and Organoleptic
Solubility	Complies	Slightly soluble in water, insoluble in ethanol, acetone and isopropyl alcohol	USP
Loss on drying	4.86 % w/w	Not more than 5.0% w/w (dried at 105°C)	Ph. Eur 2.2.32
Ash content	0.48 % w/w	Not more than 10.0% w/w	USP <561>
Sieve Test (Passes through)			USP <786>
- 40 mesh	99.74 % w/w	Not less than 95% w/w	
CHEMICAL			
Biochemical			
-Amylolytic activity - alpha amylase	29250 DU/g	Not less than 24000 DU/g (Dextrinizing Unit / gram)	SLL/STP-A-029

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Parameters	Result	Limit	Reference
-Proteolytic activity - neutral protease	7670 PC/G	Not less than 6000 PC/g (Protease Unit on L-tyrosine basis / gram)	SLL/STP-P-021
-Cellulolytic activity - cellulase	1225 CU/G	Not less than 1100 CU/g (Cellulase Unit / gram)	SLL/STP-C-021
-Beta-D-Galactosidase galactohydrolase lactase	5405 ALU/G	Not less than 4000 ALU/g (Acid Lactase Unit / gram)	SLL/STP-L-014
-Lipolytic activity - lipase	260 FIP/G	Not less than 200 FIP/g (Fungal Lipase International Unit / gram)	SLL/STP-L-016
OTHERS			
Lead	<0.20 ppm (µg/g)	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	<0.20 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	<0.20 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
Ethylene oxide (Sum of Ethylene oxide and 2-Chloroethanol)	Complies	Not more than 10ppb (µg/kg)	SLL/STP-E-015
MICROBIOLOGICAL PROFILE			

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Parameters	Result	Limit	Reference
Total aerobic microbial count	300 cfu/g	Not more than 5000cfu/g	Ph. Eur 2.6.12
Total yeasts and molds count	25 cfu/g	Not more than 100cfu/g	Ph. Eur 2.6.12
Escherichia coli	Complies	Negative/10g	Ph. Eur 2.6.13
Salmonella	Complies	Negative/10g	Ph. Eur 2.6.13
Staphylococcus aureus	Complies	Negative/10g	Ph. Eur 2.6.13
Pseudomonas aeruginosa	Complies	Negative/10g	Ph. Eur 2.6.13
Bile tolerant gram negative bacteria	<10 cfu/g	Not more than 100cfu/g	Ph. Eur 2.6.13
Coliforms	<10 cfu/g	Less than 10 fu/g	BAM Chapter 4

ADDITIONAL INFORMATION

Sanitising treatment	Non-irradiated and not treated with ETO
Certification Status (Kosher/Halal)	Kosher and Halal certified
BSE/TSE status	BSE / TSE free
Genetic Modification Status	Non-GMO
Country of Origin	India
Storage condition	Store at room temperature
Manufactured By	Sami-Sabinsa Group Limited - Peenya 19/1, 19/2, I Main II Phase, Peenya Industrial Area, Bangalore. 560 058, Karnataka, India
Manufactured At	Sami-Sabinsa Group Limited - Nelamangala No. 19/3, 20/1 & 20/2/2, Bhavikere Village, Kasaba Hobli,Nelamangala - 562123

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Remarks

Note: Gluten Free

The above certificate of analysis is based on ***Specifications Issue No: 9 Dated: October 12, 2022***

In-House developed and validated methods

NAP:Not Applicable

NAV:Not Available

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