

Product Technical Data Sheet

Product name: Bacopa Extract 20% Bacosides HPLC	AC code: I4U03984a
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1. Technical Data Sheet		
<p>Product Description:</p> <p>This product Bacopa Monnieri Extract is a natural herbal extract obtained from Bacopa monnieri, a plant traditionally used in Ayurvedic medicine for supporting cognitive and neurological health. This extract is standardized to contain not less than 20% total Bacosides, the key bioactive compounds responsible for Bacopa's functional properties.</p>		
Item	Standard	Analysis Method
Appearance & Solubility		
Appearance	Color: Greenish Brown colour* powder	Visual inspection
	Odor: Characteristic odor	Olfactory evaluation
	Taste: Characteristic taste	Sensory taste test
Solubility	Partially soluble in Water and Ethanol.	Visual inspection
Typical Analysis		
Identification	To Comply with TLC	TLC
Content of Bacosides	≥20.0%w/w	HPLC
Loss on Drying	≤ 5.0% w/w	USP < NF 2024>
Pesticides Residue	Meet EC <396/2005>	USP < NF 2024>
Sieve test	≥ 95% w/w passes through 40 mesh	USP < NF 2024>
Water Solubility	≥50.0%	USP < NF 2024>
PH 1% w/v Solution	4.0-7.0	USP < NF 2024>
Tapped Density	0.40 g/ml - 1.00 g/ml	USP < NF 2024>
Heavy metals		
Total Heavy Metals	≤ 10 ppm	USP < NF 2024>
Lead	≤ 3.0 ppm	USP < NF 2024>
Arsenic	≤ 1.0 ppm	USP < NF 2024>
Cadmium	≤ 1.0 ppm	USP < NF 2024>
Mercury	≤ 0.1 ppm	USP < NF 2024>
Microorganism		

Total Plate Count	≤10,000 cfu/g	USP < NF 2024>
Total Molds & Yeasts	≤100 cfu/g	USP < NF 2024>
Escherichia coli	Negative/10g	USP < NF 2024>
Salmonella	Negative/25g	USP < NF 2024>
Staphylococcus aureus	Negative/g	USP < NF 2024>
Pseudomonas aeruginosa	Negative/g	USP < NF 2024>
Enterobacte riaceae	Negative/g	USP < NF 2024>
Storage & Shelf Life		
Package	25 Kg packed in LDPE Double cover and packed in New HDPE drum.	
Shelf life	36 Months from the Date of Manufacturing	
Storage	In a cool and dry area away from sunlight.	

2.Origin & Ingredient

Country of origin of the product: Bacopa in India.

Origin statement: available

This product is a pure material <input checked="" type="checkbox"/>		This product is a compound material <input type="checkbox"/>	
Animal origin	<input type="checkbox"/> bovine	Specific Source: /	
	<input type="checkbox"/> porcine	Specific Source: /	
	<input type="checkbox"/> avian	Specific Source: /	
	<input type="checkbox"/> Others:	Specific Source: /	
Synthetic	<input type="checkbox"/>	Starting material:	origin:
Biotechnological processing	<input type="checkbox"/> Catalysis By Enzymes	Name Of Enzyme: /	
		Sources Of Enzymes: /	
	<input type="checkbox"/> Fermentation	Source Of Medium: /	
		Strain: /	

Botanical Origin	Botanical Name:	Bacopa Monnieri
	Part:	/
	Wild Or Cultivated:	/
	Country Of Origin:	India
	Solvent Used:	/

3. Composition Statement	
Bacopa Extract 20% Bacosides	100 %

4. GMO declaration	YES	NO (Means Not Contain)
The product does not contain or consist of GMO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced by means of GM microorganism including precursor substances, e.g. with GMOs or Genetically Modified microorganisms processing aids(bacteria, yeast,..)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced with the help of enzymes, which were obtained from GMOs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the product contain any ingredients from animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, are genetically modified crops contained in the feed for the animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO statement available		<input checked="" type="checkbox"/>

5. Allergen declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and

confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten(1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose)(4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

(1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;

(3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;

(4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;

(5) almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

6. NON IRRADIATION		
(According to EU directive 1999/2/EC & 1999/3/EC)		
This product has not been treated with ionising radiation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
None of the raw materials we used for this product have been treated with ionising radiation.	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
We confirm above Non-Irradiation statement is available	<input checked="" type="checkbox"/>	

7. NANOMATERIAL		
(according to EU Regulation (EU) No. 1169/2011)		
This product does not contain any nanomaterials as defined in EU food legislation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, does not contain
This product has not been made with nanotechnology	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, is not made with nanotechnology
We confirm above Non-Nanomaterial statement is available	<input checked="" type="checkbox"/>	

8. Residual solvents		
(according to UE Directive 2009/32 modified by (UE)2010/59; EP5.4; USP476; ICH Q3C(R7))		
For this product following solvents are used during production process: Solvent A: max residual level:	<input type="checkbox"/> solvent used <input checked="" type="checkbox"/> solvent not used	
We confirm solvent residual of this product complies with:	<input checked="" type="checkbox"/> EP 7.0 <input checked="" type="checkbox"/> USP <476>	

We confirm Solvent residual statement is available	<input checked="" type="checkbox"/>
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9.Pesticide residual	
(according to EC 396/2005; EP07; USP <561>)	
This product is of vegetable origin	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We confirm pesticide residual of this product complies with:	<input type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A
Pesticide residual statement available	<input checked="" type="checkbox"/>

10.BSE/TSE information	
(according to EU legislation 999/2001; EP general chapter 5.2.8)	
<p>Cattle, sheep, goats and animals that are naturally susceptible to infect with transmissible spongiform encephalopathy agents or susceptible to infection through the oral route other than humans and non-human primates are defined as “ESE-relevant animal species</p> <p>Pigs ad birds are not naturally susceptible to infection via the oral route; therefore, they are not TSE-relevant animal species. Dogs, rabbits and fish are not TES-relevant animal species.”</p>	
the product contains no ingredients of ruminant origin and no materials derived from, or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
In the manufacturing of this product, there is no any raw or source material and /or reagent used that is of animal origin i.e. bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
The material is not purified by using solvents, chromatographic media or	<input type="checkbox"/> YES

buffers that contain components of animal origin	<input checked="" type="checkbox"/> NO
We confirm this product complies with:	<input checked="" type="checkbox"/> EU legislation 999/2001 & <input checked="" type="checkbox"/> EP general chapter 5.2.8
We confirm BSE/TSE statement is available	<input checked="" type="checkbox"/> YES

11. Contaminants information	
(according to EU Regulation No 915/2023 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
<ul style="list-style-type: none"> ●Aflatoxin B1 <5ppb ●Aflatoxins B1 + B2 + G1 + G2 <10ppb ●Ochratoxin A <15ppb 	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
●Melamine	<input checked="" type="checkbox"/> YES
<p>For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i>:</p> <ul style="list-style-type: none"> ●Maximum level of 10 µg/kg of benzo(a)pyrene ●50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements 	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	<input checked="" type="checkbox"/> YES

12. Others
<p>We confirm we could meet with the requirement on hygiene of foodstuffs according to Reg 852/2004.</p> <p>We confirm we could meet with the requirement on general principles and requirements of food law according to REGULATION (EC) No 178/2002</p>