

FINISHED PRODUCT SPECIFICATION

PRODUCT NAME	BACOPA EXTRACT 50.0%	SPEC:FPS/B01/0510-01
		Effective Date: 04-04-2022

Botanical/ Scientific name	<i>Bacopa Monnieri</i>	Plant part used	Leaf
Standardization	Bacosides	Production Method	Drying
Shelf Life	3 years	Extraction Solvent	Ethanol

SL No	Protocol	Test Parameter	Test Limit
Physical			
01	Organoleptic	Description	Light green to brown color* powder
02	TM/0510	Identification	To Comply by HPLC
03	USP	Solubility	Partially soluble in alcohol.
04	USP <731>	Loss on drying	Not more than 7.0%w/w
05	USP <616>	Untapped bulk density	Between 0.30 to 0.60g/ml
06	USP <616>	Tapped bulk density	Between 0.40 to 0.80g/ml
07	USP <786>	Particle size	100% passing through 40 mesh
Chemical			
08	TM /0510	Content of Bacosides by HPLC	Not less than 50.0% w/w
Heavy Metal			
09	USP <233>Procedure 1	Lead	Not more than 3.0 ppm
	USP <233>Procedure 1	Arsenic	Not more than 1.0 ppm
	USP <233>Procedure 1	Cadmium	Not more than 0.5 ppm
	USP <233>Procedure 1	Mercury	Not more than 0.1 ppm
Microbiological			
10	USP <2021>	Total plate count	Not more than 3000cfu/g
	USP <2021>	Total yeast and mold count	Not more than 100cfu/g
	USP <2022>	Escherichia coli	Absent / 10g
	USP <2022>	Salmonella spp.	Absent / 10g
	USP <2021>	Coliforms	Absent / 10g
	USP <2022>	Staphylococcus aureus	Absent / 10g
	USP <62>	Pseudomonas aeruginosa	Absent / 10g

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ADDITIONAL INFORMATION	
Sanitizing treatment	Non –irradiated and not treated with ETO
GMO Status	GMO free
Standard Packing	25 Kg in single HDPE container.
Certifications	ISO 22000:2005, ISO 9001:2015, GMP, HALAL certified
Storage condition	Store in a cool and dry place away from sunlight and heat. The preferred storage is below 30 ⁰ C.

* The product is of herbal origin. There may be minor color difference because of the geographical and seasonal variations of the plant material.

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