

FINISHED PRODUCT SPECIFICATION

PRODUCT NAME	ASHWAGANDHA EXTRACT 8.0%	SPEC:FPS/B01/0102-00
		Effective Date: 11-09-2022

Botanical/ Scientific name	<i>Withania somnifera</i>	Plant part used	Root
Standardization	Withanolids	Production Method	Drying
Shelf Life	3 years	Extraction Solvent	Ethanol

SL No	Protocol	Test Parameter	Test Limit
Physical			
01	Organoleptic	Description	Light brown to dark brown color* powder
02	TM/0102	Identification	To Comply by TLC
03	USP	Solubility	Partially soluble in water
04	USP <731>	Loss on drying	Not more than 6.0% 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	NLT 95% passing through 40 mesh
Chemical			
08	TM /0102	Content of Withanolids by Gravimetry	Not less than 8.0% 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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