

FINISHED PRODUCT SPECIFICATION

PRODUCT NAME	LUTEIN EXTRACT 70.0%	SPEC:FPS/B01/0381-01
		Effective Date: 03-04-2022

Botanical/ Scientific name	Tagetes erecta	Plant part used	Petals of Marigold
Standardization	Lutein	Production Method	Drying
Shelf Life	3 years	Extraction Solvent	Ethanol

SL No	Protocol	Test Parameter	Test Limit
Physical			
01	Organoleptic	Description	Orange red to brick red color* powder
02	TM/0381	Identification	To Comply by HPLC
03	USP	Solubility	Partially soluble in alcohol.
04	USP <731>	Loss on drying	Not more than 6.0%w/w
05	USP <281>	Ash content	Not more than 5.0%w/w
06	USP <616>	Untapped bulk density	Between 0.30 to 0.60g/ml
07	USP <616>	Tapped bulk density	Between 0.50 to 0.80g/ml
08	USP <786>	Particle size	100% passing through 40 mesh
Chemical			
09	TM /0381	Content of free Lutein by HPLC	Not less than 70.0% w/w ..
Heavy Metal			
10	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			
11	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



Bio-Med Ingredients Pvt Limited

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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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