



## Specification Sheet

### Marigold Flower Extract (Lutein 5%)

Item No.:	LT001	
Country of Origin:	P. R. China	
Botanic Name:	<i>Tagetes erecta</i> L.	
Plant Parts:	Flowers	
Solvents:	Ethanol and Water	
Excipient:	Maltodextrin	
Excipient Ratio:	91%	
Shelf Life:	Two Years	
Sterilization:	Non-Irradiated/Non-ETO/Treat by Heat Only	
<b>Test</b>	<b>Specification</b>	<b>Method</b>
<b>Assay</b>		
Lutein	≥ 5.0%	HPLC
<b>Physical/Chemical</b>		
Identification	Positive	TLC
Appearance	Orange yellow powder	Visual
Odor	Characteristic	Organoleptic
Powder Size (USP)	≥ 95% through 60 mesh	USP #60 Sieve
Bulk Density	0.30 – 0.60 g/mL	USP40-NF35<616>
Loss on Drying	≤ 8.0%	USP40-NF35<731>
Residue on Ignition	≤ 2.0%	USP40-NF35<281>
Residual Solvents	USP<467>	USP40-NF35<467>
Pesticide Residues	USP<561>	USP40-NF35<561>
Aflatoxins	≤ 20 ppb	USP40-NF35<561>
<b>Heavy Metals</b>		
Total Heavy Metals	≤ 10 µg/g	USP40-NF35<231>
Arsenic (As)	≤ 1.0 µg/g	ICP-MS
Cadmium (Cd)	≤ 0.5 µg/g	ICP-MS
Lead (Pb)	≤ 1.0 µg/g	ICP-MS
Mercury (Hg)	≤ 0.5 µg/g	ICP-MS
<b>Microbiology</b>		
Total Plate Count	≤ 1,000 cfu/g	USP40-NF35<2021>
Molds and Yeasts	≤ 100 cfu/g	USP40-NF35<2021>
Total Coliforms	< 10 cfu/g	USP40-NF35<2021>
<i>Salmonella</i>	Absence	USP40-NF35<2022>
<i>E. Coli</i>	Absence	USP40-NF35<2022>
<i>Staphylococcus aureus</i>	Absence	USP40-NF35<2022>

Quality Approved By: \_\_\_\_\_

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