


Specification Sheet

<u>Milk Thistle Seed Extract (Silymarin 80% by UV, 30% by HPLC)</u>		
Item No.:	SM001	
Country of Origin:	P. R. China	
Botanic Name:	<i>Silybum marianum</i> (L.) Gaertn	
Plant Parts:	Seeds	
Shelf Life:	Two Years	
Sterilization:	Non-Irradiated	
Test	Specification	Method
Assay		
Silymarin	≥ 80%	UV-Vis
	≥ 30% (As is)	HPLC
Silybin & Isosilybin	≥ 30%	HPLC
Physical/Chemical		
Identification	Positive	TLC
Appearance	Yellowish-brown powder	Visual
Odor	Characteristic	Organoleptic
Powder Size (USP)	≥ 90% through 80 mesh	USP #80 Sieve
Bulk Density	0.30 – 0.60 g/mL	USP40-NF35<616>
Tapped Density	0.50 – 0.80 g/mL	USP40-NF35<616>
Loss on Drying	≤ 5.0%	USP40-NF35<731>
Residue on Ignition	≤ 0.5%	USP40-NF35<281>
Residual Ethyl Acetate	≤ 5,000 µg/g	USP40-NF35<467>
Residual Hexane	≤ 290 µg/g	USP40-NF35<467>
Pesticide Residues	USP<561>	USP40-NF35<561>
Aflatoxins	20 ppb	USP40-NF35<561>
Heavy Metals		
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
Microbiology		
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: 		
		Issue Date: 01-01-2018