

Certificate of Analysis

Product Name:	Silymarin/Milk Thistle P.E	Executive Standard:	USP 40
Botanical latin Name:	<i>Silybum marianum(L)</i>	Batch No:	20190618
Package:	25Kg/ Drums	Manufacturing Date:	24/06/2019
Plant Part:	Fruit	Expiry Date:	23/06/2022
Quantity:	1000KG	Report Date:	29/06/2019

No.	Test items	Specification and Standards	Results
1.	Appearance	Amorphous Powder	Conforms
2.	Colour	Yellowish-Brown	Conforms
3.	Odour	Slight, Specific	Conforms
4.	Solubility		
	- in Water	Practically Insoluble	Conforms
	- in Methanol and Acetone	Soluble	Conforms
5.	Identification		
	- TLC	To Comply with The Test	Conforms
	- HPLC	To Comply with The Test	Conforms
6.	Sulphated Ash	NMT1.0%	Conforms
7.	Heavy metals	NMT 20 PPM	Conforms
8.	Loss On Drying (2 Hours , 105 °C)	NMT 5.0%	1.90%
9.	Powder size	80Mesh, NLT90%	Conforms
10.	Assay of Total Silymarin by UV	Min 80%	80.85%
	Assay of Total Silymarin (HPLC, determined as silybin, per cent)	-	45.76%
	NLT 90.0% and NMT 110.0% of the labeled amount of silymarin.	90%~110%	100.03%
	Sum of silycrstin A and silydianin (HPLC, percent of the total content of silymarin)	20.0%~ 45.0%	28.70%
	Sum of silybin A and silybin B (HPLC, percent of the total content of silymarin)	40.0%~65.0%	57.88%
	-Sum of isosilybin A and isosilybin B (HPLC, percent of the total content of silymarin)	10.0%~20.0%	13.42%
11.	Residual Solvents (Extract Solvent-Acetone)		
	- Acetone	NMT 5000 PPM	Conforms
	- N-Hexane	NMT 290 PPM	Conforms
	-Ethanol-Ethyl Acetate-Methanol	Negative	Conforms
12.	Residual Agrichemicals		
	- Total BHC (Sum of α , β , γ and δ -BHC)	NMT 0.02 PPM	Conforms
	- Total DDT (Sum of p,p'-DDD, P,P'-DDE, o,p'-DDT and p,p'-DDT)	NMT 0.05 PPM	Conforms
	- Aldrin	NMT 0.01 PPM	Conforms
	- Endrin	NMT 0.01 PPM	Conforms
	- Dieldrin	NMT 0.01 PPM	Conforms
13.	Microbiological Quality (Total viable aerobic count)		
	- bacteria, not more than	10^4 cfu/g	20 cfu/g
	- moulds and yeasts, enterobacterial not more than	10^3 cfu/g	0 cfu/g
	-Salmonella species and Escherichia coli.	Absence	Conforms
14.	Storage :Preserve in tight, light-resistant containers, in a cool place.		
15.	Result:PASS		