



盘锦华成制药有限公司
Panjin HuaCheng Pharmaceutical Co., Ltd
检验报告
Certificate of Analysis

品名 Product Name	水飞蓟素 Silymarin Extract solvent:Acetone	批号 Batch No.	20240401w	数量 Quantity	1000kgs	生产日期 MFG Date	2024.04.01
包装 Packing	25 公斤/桶 25kgs/drum	检验日期 Analysis Date	2024.04.03	报告日期 Report Date	2024.04.08	失效日期 EXP Date	2027.03.31
项目 Items	标准 Specification		结果 Results				
使用部分: 种子(Part used:Seed)							
Assay (On Dried basis):							
Silymarin expressed as silybin stated on the label		90%-110%		101.05%			
Silycristine+Silydianine(By HPLC)		20%-45%		30.73%			
SilybinA+SilybinB(By HPLC)		40%-65%		54.26%			
IsosilybinA+IsosilybinB(By HPLC)		10%-20%		15.01%			
Spectrophotometric UV		NLT80.0%		81.20%			
Particle Size		95% Pass 80mesh		Complies			
Chemical&Physical control							
Identification		A:TLC B:HPLC		Complies			
Appearance		Amorphous Powder		Complies			
Colour		Yellowish-Brown					
Taste		Slight Characteristic		Complies			
Odor		Slight Characteristic		Complies			
Loss on drying		N.M.T.5.0%		2.04%			
Sulphated Ash		Max.1.0%		0.20%			
Solubility		in water :Practically insoluble in Methanol and Acetone :soluble		Complies Complies			
Heavy metal		N.M.T.10PPM		Complies			
Pesticide residues		Botanical Extracts(565)		Complies			
Microbiological control							
Total plate count		N.M.T.1000cfu/g		55/gr			
Yeast & mould		N.M.T.100cfu/g		25/gr			
Salmonella		Absence		negative			
E.coli		Absence		negative			
Residue solvents:							
Acetone		Max.0.5%		0.22%			
Other solvents		Max.0.05%		0.0070%			
结论 Conclusion		符合 USP43 Conforms to USP43					

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