



Chuang Song Zong Pharmaceutical Co., Ltd Ligang Plant

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CERTIFICATE OF ANALYSIS

PRODUCT : 壽美降脂一號膠囊 LipoCol Forte Capsules Manufacturing Date. : 2025/02/03

BATCH No. : SM001502

Expiry Date : 2030/02/02

DOSAGE FORM : Capsules

Date of Analysis : 2025/02/12~2025/02/21

DETERMINATION	SPECIFICATIONS	RESULT	TEST METHOD
Description	#0 reddish brown color capsule, white letters LPF on the surface, filling purple-red powder	Conform	Q08-SM001
Average Weight	700 mg $\pm$ 10 %	702.3 mg	Q08-SM001
Weight Variation	$\pm$ 10 %	Pass	Q08-SM001
Disintegration Test	$\leq$ 30 min	11'39"~14'08"	Q08-SM001
Loss on Drying	$\leq$ 9.0 %	3.35 %	Q08-SM001
Total Ash	$\leq$ 5.0 %	2.88 %	THP 4
Acid-Insoluble Ash	$\leq$ 2.0 %	0.21 %	THP 4
Dil. EtOH Extractives	$\geq$ 12.0 %	21.19 %	THP 4
H ₂ O Extractives	$\geq$ 10.0 %	23.88 %	THP 4
Total Heavy Metal	$\leq$ 30 ppm	Pass	Ph.PRC 2020
Heavy Metal Limit Test			ICP-MS,QL (mg/kg)
Arsenic (As)	< 1.0 mg/kg	0.68 mg/kg	0.1
Copper (Cu)	< 50.0 mg/kg	4.64 mg/kg	2.0
Lead (Pb)	< 5.0 mg/kg	ND	0.1
Mercury (Hg)	< 0.2 mg/kg	ND	0.05
Cadmium (Cd)	< 0.5 mg/kg	0.19 mg/kg	0.01
Pesticides Limit Test			Ph.Eur 11.
1. Total DDT	$\leq$ 0.2 mg/kg	ND	GC/MS/MS
2. Total BHC	$\leq$ 0.2 mg/kg	ND	GC/MS/MS
Microbial Limit Test			Ph.Eur 11.
Total Aerobic Microbial Count	$\leq$ 10000 CFU/g	<10 CFU/g	Ph.Eur 2.6.12
<i>E. coli</i>	Absent in 1g	Negative	Ph.Eur 2.6.13
<i>Salmonella</i>	Absent in 10g	Negative	Ph.Eur 2.6.13
Identification			Q08-SM001
Lovastatin		Positive	TLC
Assay			Q08-SM001
Lovastatin	4.79~6.61 mg/Cap.	6.47 mg/Cap.	
Citrinin Limit Test	< 1.0 μ g/g	ND	LC/MS/MS,QL(μ g/g) 0.12

Doc. No.:Q08-SM001-7.2 ; Version No.:02

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Shu-Tuan Chiang
2025.02.25

Shu-Tuan Chiang

Manager of Q.A. Dept.