



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. : 2022/01/06

BATCH No. : SM001201

Expiry Date : 2027/01/05

DOSAGE FORM : Capsules

Date of Analysis : 2022/01/28

DETERMINATION	SPECIFICATIONS	RESULT	TEST METHOD
Description	#0 Deep red color capsule, filling purple-red powder	Conform	Q08-SM001
Average Weight	700 mg $\pm$ 10 %	704.60 mg	Q08-SM001
Weight Variation	$\pm$ 10 %	Pass	Q08-SM001
Disintegration Test	$\leq$ 30 min	19'26"~23'15"	Q08-SM001
Loss on Drying	$\leq$ 9.00%	3.57 %	Q08-SM001
Total Ash	$\leq$ 5.00%	2.92 %	THP 4
Acid-Insoluble Ash	$\leq$ 2.00%	0.04 %	THP 4
Dil. EtOH Extractives	$\geq$ 12.00%	23.09 %	THP 4
H <sub>2</sub> O Extractives	$\geq$ 10.00%	23.16 %	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	0.61 mg/kg	0.1
Copper (Cu)	< 50.0 mg/kg	4.91 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	0.17 mg/kg	0.01
Pesticides Limit Test			Ph.Eur 10.
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 10.
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.	6.14 mg/Cap.	HPLC
Citrinin Limit Test	< 1.0 $\mu$ g/g	ND	LC/MS/MS,QL( $\mu$ g/g) 0.12

Doc. No.:Q08-SM001-07 ; Version No.:02

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Shu-Tuan Chiang  
2022.02.15

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Manager of Q.A. Dept.