



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. : 2024/01/02
BATCH No. : SM001401 Expiry Date : 2029/01/01
DOSAGE FORM : Capsules Date of Analysis : 2024/01/11~2024/01/19

DETERMINATION	SPECIFICATIONS	RESULT	TEST METHOD
Description	#0 Deep red color capsule, filling purple-red powder	Conform	Q08-SM001
Average Weight	700 mg±10 %	702.25 mg	Q08-SM001
Weight Variation	± 10 %	Pass	Q08-SM001
Disintegration Test	≤ 30 min	11'53"~16'07"	Q08-SM001
Loss on Drying	≤ 9.00%	4.74 %	Q08-SM001
Total Ash	≤ 5.00%	2.90 %	THP 4
Acid-Insoluble Ash	≤ 2.00%	0.33 %	THP 4
Dil. EtOH Extractives	≥ 12.00%	21.32 %	THP 4
H ₂ O Extractives	≥ 10.00%	23.44 %	THP 4
Total Heavy Metal	≤ 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	4.82 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	0.20 mg/kg	0.01
Pesticides Limit Test			Ph.Eur 11.
1. Total DDT	≤ 0.2 mg/kg	ND	GC/MS/MS
2. Total BHC	≤ 0.2 mg/kg	ND	GC/MS/MS
Microbial Limit Test			Ph.Eur 11.
Total Aerobic Microbial Count	≤ 10000 CFU/g	2.6×10 ² 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.	6.57 mg/Cap.	
Citrinin Limit Test	< 1.0 µg/g	ND	LC/MS/MS,QL(µg/g) 0.12

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

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Shu-Tuan Chiang
2024.01.24

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Manager of Q.A. Dept.