



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. : 2021/04/30

BATCH No. : SM001104

Expiry Date : 2026/04/29

DOSAGE FORM : Capsules

Date of Analysis : 2021/05/27

DETERMINATION	SPECIFICATIONS	RESULT	TEST METHOD
Description	#0 Deep red color capsule, filling purple-red powder	Conform	Q08-SM001
Average Weight	700 mg±10 %	704.10 mg	Q08-SM001
Weight Variation	± 10 %	Pass	Q08-SM001
Disintegration Test	≤ 30 min	9'27"~13'22"	Q08-SM001
Loss on Drying	≤ 9.00%	3.64 %	THP 3
Total Ash	≤ 5.00%	2.93 %	THP 3
Acid-Insoluble Ash	≤ 2.00%	0.13 %	THP 3
Dil. EtOH Extractives	≥ 12.00%	23.54 %	THP 3
H ₂ O Extractives	≥ 10.00%	22.88 %	THP 3
Total Heavy Metal	≤ 30 ppm	Pass	Ph.PRC 2020
Heavy Metal Limit Test			ICP-MS,QL (mg/kg)
Arsenic (As)	< 1.0 mg/kg	0.56 mg/kg	0.1
Copper (Cu)	< 50.0 mg/kg	4.90 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	0.18 mg/kg	0.01
Pesticides Limit Test			Ph.Eur 10.
1. Total DDT	≤ 0.2 ppm	ND	GC/MS/MS
2. Total BHC	≤ 0.2 ppm	ND	GC/MS/MS
Microbial Limit Test			Ph.Eur 10.
Total Aerobic Microbial Count	≤ 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.	6.52 mg/Cap.	HPLC
Citrinin Limit Test	< 1.0 ppm	ND	LC/MS/MS,QL(ppm) 0.12

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2021.06.02

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