



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. : 2024/05/16
BATCH No. : SM001407 Expiry Date : 2029/05/15
DOSAGE FORM : Capsules Date of Analysis : 2024/05/30~2024/06/07

DETERMINATION	SPECIFICATIONS	RESULT	TEST METHOD
Description	#0 Deep red color capsule, filling purple-red powder	Conform	Q08-SM001
Average Weight	700 mg±10 %	703.81 mg	Q08-SM001
Weight Variation	± 10 %	Pass	Q08-SM001
Disintegration Test	≤ 30 min	11'49"~15'27"	Q08-SM001
Loss on Drying	≤ 9.0 %	4.21 %	Q08-SM001
Total Ash	≤ 5.0 %	2.99 %	THP 4
Acid-Insoluble Ash	≤ 2.0 %	0.24 %	THP 4
Dil. EtOH Extractives	≥ 12.0 %	22.90 %	THP 4
H ₂ O Extractives	≥ 10.0 %	20.97 %	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	0.64 mg/kg	0.1
Copper (Cu)	< 50.0 mg/kg	4.57 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	0.15 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	70 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.	6.10 mg/Cap.	
Citrinin Limit Test	< 1.0 µg/g	ND	LC/MS/MS,QL(µg/g) 0.12

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Shu-Tuan Chiang
2024.06.18

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Manager of Q.A. Dept.