



Chuang Song Zong Pharmaceutical Co.,Ltd Ligang Plant

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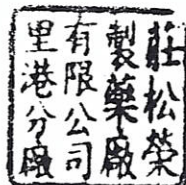
CERTIFICATE OF ANALYSIS

PRODUCT : 壽美降脂一號膠囊 LipoCol Forte Capsules Manufacturing date. : 2019/02/14
BATCH No. : SM001901 Expiry date : 2024/02/13
DOSAGE FORM : Capsules Date of analysis : 2019/03/21

DETERMINATION	SPECIFICATIOIS	RESULT	TEST METHOD
Description	#0 Deep red color capsule, filling purple-red powder	Conform	Q08-SM001
Average Weight	700mg±10%	704.8mg	Q08-SM001
Weight variation	± 10%	Pass	Q08-SM001
Disintegration test	≤ 30 min	15'06"~18'52"	Q08-SM001
Loss On Drying	≤ 9.00%	2.54%	THP 2
Total Ash	≤ 5.00%	2.90%	THP 2
Acid-Insoluble Ash	≤ 2.00%	0.23%	THP 2
Dil. EtOH Extract	≥ 12.00%	22.55%	THP 2
H ₂ O Extract	≥ 10.00%	22.66%	THP 2
Total Heavy Metal	≤ 30 ppm	Pass	Ph.PRC 2015
Heavy Metal Limit Test			ICP-MS,QL (mg/kg)
Arsenic (As)	< 1.0 mg/kg	0.63 mg/kg	0.1
Coppers (Cu)	< 50.0 mg/kg	5.17 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	0.30 mg/kg	0.01
Pesticides Limit Test			Ph.Eur 9.
1. Total DDT	≤ 0.2ppm	ND	GC/MS/MS
2. Total BHC	≤ 0.2ppm	ND	GC/MS/MS
Microbial Limit Test			Ph.Eur 9.
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 lovastatin		Positive	Q08-SM001 TLC
Assay lovastatin	4.79~6.61mg/Cap.	6.04 mg/Cap.	Q08-SM001 HPLC
Citrinin Limit Test	< 1.0ppm	ND	LC/MS/MS,QL(ppm) 0.12

Doc. No.:Q08-SM001-06 ; Version No.:02

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Shu-Tuan Chiang
2019.03.26

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Manager of Q.A. Dept.