



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. : 2019/06/20

BATCH No. : SM001902

Expiry date : 2024/06/19

DOSAGE FORM : Capsules

Date of analysis : 2019/07/17

DETERMINATION	SPECIFICATIOIS	RESULT	TEST METHOD
Description	#0 Deep red color capsule, filling purple-red powder	Conform	Q08-SM001
Average Weight	700mg±10%	705.27mg	Q08-SM001
Weight variation	± 10%	Pass	Q08-SM001
Disintegration test	≤ 30 min	16'18"~24'00"	Q08-SM001
Loss On Drying	≤ 9.00%	2.62%	THP 3
Total Ash	≤ 5.00%	3.08%	THP 3
Acid-Insoluble Ash	≤ 2.00%	0.35%	THP 3
Dil. EtOH Extract	≥ 12.00%	22.45%	THP 3
H ₂ O Extract	≥ 10.00%	23.56%	THP 3
Total Heavy Metal	≤ 30 ppm	Pass	Ph.PRC 2015
Heavy Metal Limit Test			ICP-MS,QL (mg/kg)
Arsenic (As)	< 1.0 mg/kg	0.58 mg/kg	0.1
Coppers (Cu)	< 50.0 mg/kg	4.81 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	0.26 mg/kg	0.01
Pesticides Limit Test			Ph.Eur 9.
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 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			Q08-SM001
lovastatin		Positive	TLC
Assay			Q08-SM001
lovastatin	4.79~6.61mg/Cap.	6.00 mg/Cap.	HPLC
Citrinin Limit Test	< 1.0ppm	ND	LC/MS/MS,QL(ppm) 0.12

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Shu-Tuan Chiang 2019.07.25

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Manager of Q.A. Dept.