



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. : 2023/01/03  
BATCH No. : SM001301 Expiry Date : 2028/01/02  
DOSAGE FORM : Capsules Date of Analysis : 2023/01/13~2023/02/07

| DETERMINATION                    | SPECIFICATIONS  | RESULT        | TEST METHOD               |
|----------------------------------|---|---------------|---------------------------|
| Description                      | #0 Deep red color capsule,<br>filling purple-red powder | Conform       | Q08-SM001                 |
| Average Weight                   | 700 mg±10 %   | 704.05 mg     | Q08-SM001                 |
| Weight Variation                 | ± 10 %  | Pass          | Q08-SM001                 |
| Disintegration Test              | ≤ 30 min  | 13'29"~16'22" | Q08-SM001                 |
| Loss on Drying                   | ≤ 9.00%   | 4.35 %        | Q08-SM001                 |
| Total Ash                        | ≤ 5.00%   | 2.92 %        | THP 4                     |
| Acid-Insoluble Ash               | ≤ 2.00%   | 0.30 %        | THP 4                     |
| Dil. EtOH Extractives            | ≥ 12.00%  | 21.75 %       | THP 4                     |
| H <sub>2</sub> O Extractives     | ≥ 10.00%  | 23.51 %       | 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   | 0.57 mg/kg    | 0.1                       |
| Copper (Cu)                      | < 50.0 mg/kg  | 4.67 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   | 0.17 mg/kg    | 0.01                      |
| Pesticides Limit Test            |   |               | Ph.Eur 10.                |
| 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 10.                |
| Total Aerobic Microbial<br>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.                                       | 5.84 mg/Cap.  | HPLC                      |
| Citrinin Limit Test              | < 1.0 µg/g  | ND            | LC/MS/MS,QL(µg/g)<br>0.12 |

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2023.02.15

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Manager of Q.A. Dept.