fimea

Lääkealan turvallisuus- ja kehittämiskeskus
Säkerhets- och utvecklingscentret
för läkemedelsområdet
Finnish Medicines Agency

Certificate No: 30/06.08.02.00/2018

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1]

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Finland confirms the following:

The manufacturer: Hunan Yuantong Pharmaceutical Co. Ltd.

Site address: No. 747, Kangwan Road, Liuyang Economic Development Zone
China-410 331 Changsha City, Hunan Province

Is an active substance manufacturer that has been incpected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: Medicines Act and Medicines Decree, Finland.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on the 6th - 8th of February 2018, it is considered that it complies with the principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact issuing authority.

Turku 19th June 2018

Kari Lönnberg, Senior Pharmaceutical Inspector,
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[1]The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, is also applicable to importers.
[2] Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database
[3]These requirements fulfil the GMP recommendations of WHO

Part 2

☒ Human Medicinal Products

3	**MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES** Active Substance: Diosmin
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : acid addition, filtration, washing
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: blending, micronizing 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substances) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality control testing**
	3.6.1 Chemical/Physical 3.6.2 Microbiological testing excluding sterility testing

Any restrictions or clarifying remarks related to the scope of this certificate:

Turku 19th June 2018

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