

Certificate No: 1288/06.08.02.00/2016

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CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER¹

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: **HUBEI BIOCAUSE HEILEN PHARMACEUTICAL COMPANY LIMITED**

Site address: **122-132 YANGWAN ROAD, JINGMEN, CN-448 000, China**

Is an active substance manufacturer that has been inspected 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 13th of April 2016, it is considered that it complies with the principles of GMP for active substances³ 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 Eudra GMDP. If it does not appear, please contact issuing authority.

Helsinki 28th June 2016



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¹The 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.

²Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database

³These requirements fulfil the GMP recommendations of WHO

Part 2

☒ Human Medicinal Products

3	MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES Active Substance: TORASEMIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
3.5	General Finishing Steps
	3.5.1 Physical processing steps: eg. milling, sieving
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: Torasemide facility



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