fimea

Certificate No: 001149/06.08.02.00/2019

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1,2]

Part 1

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

The competent authority of Finland confirms the following:

The manufacturer: Atabay Kimya Sanayi ve Ticaret A.S.

Site address: Acibadem, Koeftuenci Sokak No. 1, Kadikoey, Istanbul, 34718, Turkey

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 28th March 2019, it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3]

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 and validity of this certificate should be verified in EudraGMDP database eudragmp.ema.europa.eu. If it does not appear, please contact issuing authority.

Helsinki 23th August 2019

Anne Junttonen, Head of Unit,
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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, shall also be required for imports coming from third countries into a Member State.
[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	
1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets 1.2.1.17 Other: Direct compression granules
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate:
This certificate is valid only for Paracetamol DC granules and Paracetamol tablets

Helsinki 23th August 2019

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