

Danish Medicines Agency

Report No: **DK API-H 00096318**

STATEMENT OF NON-COMPLIANCE WITH GMP

*Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer*¹

Part 1

Issued following an inspection in accordance with :
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Denmark confirms the following:

The manufacturer: ***Kadam Exports Private Ltd.***

Site address: ***205-207, G.I.D.C. Estate, Mehsana, Gujarat, 384002, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-12-07***, it is considered that ***it does not comply with the Good Manufacturing Practice*** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC .

¹ *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

Part 2

1 NON-COMPLIANT MANUFACTURING OPERATIONS

Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

1.4	Other products or manufacturing activity
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	<i>1.4.1 Manufacture of</i>
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	1.4.1.4 Other: Herbal API(en)
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Manufacture of active substance. Names of substances subject to non-compliant :

PSYLLIUM HUSK(en)

4. Non-Compliant Other Activities - Active Substances :

API bulk Psyllium HUSK is an herbal product consisting of plant fibers for dietary and herbal medicinal products

Part 3

1. Nature of non-compliance:

A general lack of ability to adhere to the principles of good manufacturing practices for production facilities, laboratory facilities and storage of reference and retention samples. Examples of non-adherence are: The production facilities were not appropriate for GMP use. There was a big risk of contamination of products. The whole facility was not in a protected and controlled environment. Also the laboratory facilities were not in a protected and controlled environment. Reference and retention samples were not stored in a controlled container. The personnel was not trained in EU GMP guidelines. As a result the quality of the product is not ensured.

Action taken/proposed by the NCA

Recall of batches already released

Based on a risk assessment and due to the general nature of the non-adherence issues observed we do not recommend recall of medicinal products already in the market at this point.

Others

Previous GMP certificate No DK API-H 00049515 will not be renewed

Additional comments

To the knowledge of the Danish Medicines Agency Psyllium HUSK manufactured at Kadam Exports Private Ltd. is only used as an API in Denmark

2018-01-25

Name and signature of the authorised person of the
Competent Authority of Denmark

Confidential
Danish Medicines Agency
Tel: *Confidential*
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