Health and Youth Care Inspectorate – Pharmaceutical Products

Report No: ***NL/H19/2003259***

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 Netherlands confirms the following:
The manufacturer: ***Pharma Essentials Production B.V.***
Site address: ***Hermelijnkoog 44, ALKMAAR, 1822CB, Netherlands***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-18*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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

Human Medicinal Products

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;

1.5	Packaging
	1.5.1 Primary Packing 1.5.1.17 Other non-sterile medicinal products: packaging of powders in 100 grams containers(en)
	1.5.2 Secondary packing

Part 3

1. Nature of non-compliance:

During the Inspection performed in the period 18 September 2019 at Pharma Essentials Production B.V. Hermelijnkoog 44, Alkmaar, twelve (12 deficiencies were identified in total, one deficiency (n=1) was classified as critical and two deficiencies (n=2) as major. Pharma Essentials Production B.V. showed a lack of ability to adhere to the principles of Good Manufacturing Practice, according to the following subjects (only the critical and major deficiencies are summarized): 1. Pharma Essentials Product B.V. did not take sufficient technical, organizational and procedural measures to control the risk for cross-contamination when working with active substances for drug product products for human use during the primary packaging of powders in the manufacturing areas number 1 and number 2 and the powder handling cabinet in the goods transfer area leading into manufacturing area number 1. 2. The quality management system of Pharma Essentials Production B.V. does not consist of the relevant elements as defined in Chapter 1, 8 and 9 of the GMP. Risk management and management review are not implemented, trend analysis is not performed, changes are not or insufficiently reported, self-inspections are not reported. Therefore the senior management and the QP lack sufficient overview of the functioning of the quality management system. 3. The training of the personnel is not according the requirements in Chapter 2 of the GMP. As a result of this, the quality of the products manufactured at the site is not ensured.

Action taken/proposed by the NCA

Recall of batches already released
Recall of batches is recommended.

Prohibition of supply
Suspension of the distribution of Glaubersalt (Natrium Sulphate decahydrate) and Bittersalt (Magnesium Sulphate heptahydrate).

Others
The GMP certificate NL/H 15/1003323 restricted to Glaubersalt (Natrium Suphate decahydrate) and Bittersalt (Magnesium Sulphate heptahydrate) related to manufacturing authorization 6266 F has been withdrawn prior to issueing of the non-compliance report. Suspension of all licensed activities until a sufficient GMP level has been installed and confirmed by the NCA.

2019-11-19

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

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