Medicines Authority

Report No: ***MT/001NCR/2017***

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 Malta confirms the following:
The manufacturer: ***Gopaldas Visram & Co. Ltd.***
Site address: ***Plot No. A/327, TTC Industrial Area, M.I.D.C., Mahape, Navi Mumbai, Maharashtra, 400701, India***
DUNS Number: ***85-803-0888***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-05-17*** , 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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: powders, granules(en) 1.2.1.11 Semi-solids
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: powders, granules(en) 1.5.1.11 Semi-solids
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

4. Non-Compliant Other Activities - Active Substances :
N/A

Part 3

1. Nature of non-compliance:

First GMP inspection performed by an EU Competent Authority at this site was on 13th – 17th May 2017. During this inspection, the inspectors found two critical, four major and thirty seven other deficiencies. The first critical deficiency was cited with regards to data integrity. E.g. Login details for the QA Manager were shared with a delegate. Employees have administrator rights to GMP related softwares (HPLC, stability chambers datasoft system). Controlled documents were found torn in a bin where used clothes are disposed-of. Records were not adequately stored to ensure their preservation and facilitate retrieval. Fire risks had not been addressed. Pest and rodent control treatment procedure included chemicals not fit for a manufacturing facility of medicinal products but used for disinfection of beds, bed frames, restaurants and mattresses. The second critical deficiency was cited with regards to risk management and data integrity. The company is not identifying and mitigating its risks. No risk assessment has been carried out for cross-contamination. A document assessing risks of packaging activities was presented which referred to processes and risks that were not present at the facility and therefore evidently the risk assessment document did not belong to the site. Major deficiencies were cited with regards to supplier qualification; validations and qualifications; clean equipment storeroom design; stability programme and standard preparation at the QC lab. The company has large gaps in their qualification and validation activities. Examples, amongst others, included: process validation documents are copies, presented as originals, belonging to a client (the product owner); no process validation reports were available for several products; documents for IQ and OQ of a packaging machine were signed by people who, it was claimed, had left the company but the company was unable to provide any verification of who the signatures belonged to; clean equipment is stored in an area that is open to a technical area with an HVAC unit with no pressure cascade; the stability chambers settings are not protected and the documentation of a standard preparation was not adequate.

Action taken/proposed by the NCA

Others

No marketing authorisation applications, line extensions or variations to existing or pending marketing authorisations applications should be authorised with this site as a new site of manufacture.

Additional comments

Since this site does not have a valid EU GMP certification no medicinal products should be on the European market. However the company stated during the course of the inspection that some of their medicinal products for external use are already on the US market.

2017-08-29

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

---

Confidential
Medicines Authority
Tel: ***Confidential***
Fax: ***Confidential***