

Medicines and Healthcare Products Regulatory Agency

Report No: *UK MIA 17907 Insp GMP 17907/13988-0025 NCR*

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 United Kingdom confirms the following:

The manufacturer: **BRISTOL LABORATORIES LIMITED**

Site address: **LAPORTE WAY, LUTON, LU4 8WL, United Kingdom**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-07-17**, 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
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

2 NON-COMPLIANT IMPORTATION OPERATIONS

2.1	Quality control testing of imported medicinal products
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Clarifying remarks (for public users)

The scope of this statement of non-compliance is limited to medicinal products considered non-critical to public health. Where manufacture and/or testing is continued for critical products, this should be supported by a documented risk assessment containing sufficient information to support activity on a risk management basis.

Part 3

1. Nature of non-compliance:

The inspection in July 2017 identified two critical deficiencies relating to the integrity and recording of GMP critical data and with the ongoing stability monitoring programme.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. UK MIA 17907 Insp GMP 17907/13988-0024

Withdrawal of previous GMP Certificate No: UK MIA 17907 Insp GMP 17907/13988-0024. Issue of a statement of non-compliance and restricted GMP certificate will be issued to permit continued manufacture and testing of products considered to be medically critical or to ensure continuity of supply, as determined by the national competent authority. Due to the nature of the issues identified batches of any non-critical products not released to market are included in the scope of this SNC.

Prohibition of supply

No batches of non-critical product to be supplied to EU markets whilst this statement of non-compliance remains in force.

2017-08-24

Name and signature of the authorised person of the
Competent Authority of United Kingdom

Confidential

Medicines and Healthcare Products Regulatory Agency

Tel: *Confidential*

Fax: *Confidential*