Medicines and Healthcare products Regulatory Agency

Report No : Insp GMP/IMP 46334/14567004-0007

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

- Regulation 331 of The Human Medicines Regulations 2012 (SI 2012/1916)
- Regulation 2 of the current Veterinary Medicines Regulations
- Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following:
The Manufacturer: Marfleet Analytical Services Limited

Site address:

Marfleet Analytical Services Limited, Wyke House, Wyke Works, Hedon Road, Hull, HU9 5NL, UNITED KINGDOM

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***17/05/2022*** , 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 Regulation B17(3) of the Human Medicines Regulations 2012 (as amended)
- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17(3) and C17 of The Human Medicines Regulations 2012 (SI 2012/1916)
- The principles and guidelines of Good Manufacturing Practice laid down in Regulation 2 of the current Veterinary Medicines Regulations

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Part 2

Human Medicinal Products Veterinary Medicinal Products Human Investigational Medicinal Products
1. MANUFACTURING OPERATIONS [1.6] Quality control testing [1.6.3] Chemical/Physical 2. IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

Restrictions or remarks: None

Part 3

Nature of non-compliance :
The company failed to operate a compliant GMP quality management system. This was identified during inspection Insp GMP/IMP 46334/14567004-0005. Over two subsequent inspections the company could not demonstrate that all CAPA actions committed to in response to the initial inspection had been implemented, and that the CAPA which had been implemented were effective.

Action taken/proposed:
revocation

Withdrawal of current valid GMP certificates:
UK GMP 46334 Insp GMP/IMP 46334/14567004-0006 [H] and UK GMP 46334 Insp GMP/IMP 46334/14567004-0006 [V]

Marketing authorisation value:
Requested variation

Marketing authorisation action :
Marketing authorisation holders should remove the laboratory from applicable authorisations by variation.

30/06/2023	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential