Medicines and Healthcare products Regulatory Agency

Report No : Insp GMP 52165/19076958-0001

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)

The competent authority of United Kingdom confirms the following:
The Manufacturer: Geno Pharmaceuticals Private Limited

Site address:

Geno Pharmaceuticals Private Limited, Tivim Industrial Estate, Karaswada, Mapusa, Goa, IN-403526, INDIA

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***23/06/2026*** , 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)

Part 2

Human Medicinal Products
1. MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.13] Tablets [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.13] Tablets [1.5.2] Secondary packing [1.6] Quality control testing

MHRA-GMDP MHRA

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Restrictions or remarks: The inspection scope encompassed manufacturing, packaging, warehousing and QC operations within the non sterile solid dosage facility. Activities relating to semi solid dosage forms were excluded from the scope of this inspection.

Part 3

Nature of non-compliance :
An unannounced inspection of the facility was conducted from 15 to 23 June 2026. This inspection was triggered following three Class II recalls of medicinal products supplied to the UK market. Five critical deficiencies were identified, including: - Senior Management had failed to ensure that there was a comprehensively designed and correctly implemented Pharmaceutical Quality System - Lack of adequate and effective procedures and controls to prevent mix-ups and substitution of materials - Failure to ensure that risks of contamination and cross-contamination were assessed and minimised - Deficiencies in the management and investigation of serious quality defects - Generation and retention of unreliable GMP records, compromising data integrity and assurance of product quality

Withdrawal of current valid GMP certificates:
The site does not hold a manufacturing authorisation because it is located in a 3rd country. The MHRA has not issued a GMP certificate for this site. EU Competent Authorities should consider a withdrawal of the current EU GMP certificate.

Prohibition of supply:
No further batches to be supplied to the UK market until an inspection confirms adequate corrective and preventative actions have been taken.

25/06/2026	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential

MHRA-GMDP MHRA