Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

Stallion Laboratories Pvt Ltd (Unit-II)
Gallops Industrial Park-II
Plot no. D-4,5,6,17,18 & 19
Changodar Bavla Highway
Ahmedabad 382110
Gujarat
India

Head Office:
Inspection, Enforcement & Standards Division, MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Telephone: 020 3080 6000
Email: info@mhra.gov.uk

Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Initial inspection of a new site named on a UK MA

Licence or Reference Number: [redacted] and [redacted]

Licence Holder/Applicant: Stallion Laboratories Pvt Ltd (Unit-II)

Details of Products: Manufacture and packaging of tablets

Activities carried out by company:	Y/N
Manufacture of Active Ingredients	N
Manufacture of Finished Medicinal Products – Non-sterile	Y
Manufacture of Finished Medicinal Products – Sterile	N
Manufacture of Finished Medicinal Products – Biologicals	N
Manufacture of Intermediate or Bulk	Y
Packaging – Primary	Y
Packaging – Secondary	Y
Importing	N
Laboratory Testing	Y
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other:	N

Name and Address of sites inspected (if different to cover):

Site Contact: [redacted]

Dates of Inspection: 14-15 Dec 2023

Lead Inspector: [redacted]

Accompanying Inspector: [redacted]

Case Folder References: Insp GMP 56600/28239676-0001

Section B General Introduction

B1 Background information

Stallion Laboratories was established in 1988 with its headquarters in Ahmedabad. The company had two manufacturing units located in the city. Unit I was accredited by WHO [redacted]. Unit II was constructed in 2020 and was intended to supply [redacted] It was stated that the facility had been inspected by US FDA in early 2023. This was the first inspection by a UK or European regulatory authority.

The UK MA holder for [redacted] was [redacted]

Previous Inspection Dates: N/A – first MHRA inspection

Previous Inspectors: N/A – first MHRA inspection

C13 Distribution and shipment (including WDA activities if relevant)

Samples for UK import testing were to be taken by [redacted] The QTA with [redacted] did not contain information as to where the product was to be shipped, how the products were to be palletised or the shipping route expected.

C14 Questions raised by the Assessors in relation to the assessment of a marketing authorisation

None

C15 Annexes attached

Annex 1 site risk rating

Section D List of Deficiencies

D1 Critical

None

D2 Major

None

D3 Others

3.1 Quality control operations were deficient, in that:

3.1.1 The raw material sampling procedure allowed up to 20 samples to be used for a composite.

3.1.2 The validation of spreadsheets was incomplete, as there was no documented record of the operating system used at the time of the validation, or which computer had been used.

3.1.3 Microbiological media preparation records did not include checked calculations to ensure the manufacturer's label instructions were correctly converted into the amounts dispensed.

3.1.4 There was no requirement to monitor the temperature of melted agar to ensure that it was prepared in accordance with the manufacturer's instructions.

3.1.5 Stability operations were deficient, as evidenced by:

3.1.5.1 [redacted] stability samples were not labelled in accordance with [redacted]

3.1.5.2 There was no clear segregation of different batches in the stability chamber, some of which were noted to be loose blister strips.

3.1.6 CAPA effectiveness check [redacted] did not describe the evaluation criteria, and therefore it was not clear how the effectiveness could be demonstrated.

Reference: EU GMP 1.4 (xiv), 6.13, 6.19, Annex 8 (4)

3.2 The risks from cross-contamination were not minimised, as evidenced by:

3.2.1 The procedure for manual cleaning of the dispensing equipment was not sufficiently detailed to ensure a consistent clean would be obtained. In addition, there was no instruction that nylon scrubbers were single use only.

3.2.2 There was no provision for the disposal of contaminated lint free cloths in the dispensary wash area.

3.2.3 The AHU pre-filter cleaning procedure and records were not sufficiently detailed to demonstrate that the cleaning was always carried out in a consistent manner.

Reference: EU GMP 3.36, 3.37

3.3 Processes to ensure emerging trends were identified, investigated and mitigated were deficient:

3.3.1 The 2022 PQR and the stability reporting arrangements for [redacted] did not identify or discuss what appeared to be an upward stability trend for total impurities.

3.3.2 It was not clear from [redacted] how recommendations and CAPA arising from the PQR would be tracked and actioned other than through a review at the next PQR time point.

3.3.3 There was no requirement to trend purified water results and therefore it was not clear how trends from individual usage points would be identified.

Reference: EU GMP 1.10 (vii), 1.11, 6.26

3.4 Outsourced and contractual arrangements were incomplete, as evidenced by:

3.4.1 The Quality Technical Agreement with [redacted] was deficient in that:

3.4.1.1 There was limited information regarding distribution of the product as it was not specified where the batches would be shipped to.

3.4.1.2 The agreement described arrangements for the contract acceptor's QP, however this was not applicable to third country manufacturers such as Stallion.

Reference: EU GMP 7.14, 7.15

3.5 Control of starting materials was deficient, in that:

3.5.1 The vendor approval procedure [redacted] stated that domestic vendors could be periodically reassessed by questionnaire and audit, whereas overseas vendors were reassessed by questionnaire only. This appeared to be based solely on location rather than risk.

3.5.2 Excipient risk assessments did not include factors such as supply chain complexity, or whether there had been any known quality defects/fraudulent adulterations in the marketplace. For example, but not limited to, [redacted] and [redacted] for [redacted]

Reference: EU GMP 5.27, 5.29

D4 Comments

4.1 The company are requested to inform the inspectors [redacted]

Section E Site Oversight Mechanism

Site referred or to be monitored by:	Tick (✓)	Referral date	Summary of basis for action
Risk Based Inspection Programme	✓	[redacted]	[redacted]
Compliance Management Team			
Inspection Action Group			