



**Medicines & Healthcare products
Regulatory Agency**



INSPECTION REPORT

Baxter Pharmaceuticals India Private Limited,
Chacharwadi Vasana
Sarkhej-Bavla Road
Sanand District
Ahmedabad
Gujarat
India

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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Routine Re-Inspection

Licence or Reference Number:



Licence Holder/Applicant: Baxter Heaalthcare Ltd

Details of Product(s)/ Clinical trials/Studies: See section B1

Activities carried out by company:	Y/N
Manufacture of Active Ingredients	N
Manufacture of Finished Medicinal Products – Non sterile	N
Manufacture of Finished Medicinal Products - Sterile	Y
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	Y
Broker	N
Other	N

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

Site Contact:

Date(s) of Inspection: 5th – 9th February 2024

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Lead Inspector: [REDACTED]

Accompanying Inspector(s): [REDACTED]

Case Folder References: Insp GMP 20752-13875-0015

Section D List of Deficiencies

D1 Critical

None

D2 Major

None

D3 Others

3.1 Documentation practices were deficient in that:

3.1.1 A number of alterations to written raw data in various data capture documents although attributable, did not have a written explanation for the alteration.

3.1.2 Loss of traceability was observed for the printout of endotoxin drying for the test [REDACTED], as it was split into two with the second part appended without reference to serial no/equipment/test noted on the raw data.

Reference: EU GMP C4.8, 4.9

3.2 Quality Control was deficient in that:

3.2.1 Pipette calibrations were not reported in the as-found state by the third-party calibrator. In addition, the company had not considered the potential damage to pipettes during transport back from the calibrator.

Reference: EU GMP C3.41

3.3 Recall was deficient in that:

3.3.1 Recall [REDACTED] was closed without appropriate confirmation of reconciliation data from Australia.

Reference: EU GMP C8.29

3.4 Vendor assurance was deficient in that:

3.4.1 The site were unable to demonstrate that the performance of [REDACTED] the supplier of cleanroom garments, was acceptable in that: whilst periodic reports were received from the supplier, there was no evidence of review and assessment of the records and the results related to the outsourced activities.

Reference: EU GMP C7.7, 7.8

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D4 Comments

None