Medicines & Healthcare products
Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

ERAMOL (UK) LIMITED

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UNIT 11
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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Re-inspection of recently opened main site (Sevenoaks site 26807038) and routine re-inspection of the small existing site (Gatwick site 18209389).

Licence or Reference Number: MIA(IMP), MIA, MS, WDA(H) 49160

Licence Holder/Applicant: Eramol (UK) Ltd

Details of Product(s)/ Clinical trials/Studies: Small scale clinical trial manufacture and packaging

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	N
Packaging – Primary	Y
Packaging – Secondary	Y
Importing	Y
Laboratory Testing	Y
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other: *IMP activities (small scale manufacture and packaging including blinding)*	Y

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

Sevenoaks site number 26807038 (newer site – base for inspection):
Unit 9 North Downs Business Park, Sevenoaks, Kent TN13 2TL

Gatwick site number 18209389 (older site):
Unit 11 Gatwick Metro Centre, Balcombe Road, Horley, Surrey, RH6 9GA

Site Contact: [redacted]

Date(s) of Inspection: 23rd to 26th January 2024 (3 days)

Lead Inspector: [redacted]

Accompanying Inspector(s): [redacted]

Case Folder References: Insp GMP/GDP/IMP 49160/26807038-0008

Section D List of Deficiencies

1 Critical

None

2 MAJOR

None

3 OTHERS

3.1 **The control of documents was deficient, as evidenced by;**
3.1.1 Batch records
3.1.1.1 Batch record photographs and/or descriptions for label placement were not appropriately clear, or sufficiently detailed to minimise the risk of unblinding.
3.1.1.2 Retention sample photos in completed batch records (the principal GMP record) were not fully legible.
3.1.1.3 There was no comment documented in [redacted] as to why a range of kit numbered labels were no longer required.
3.1.2 Quality Agreement [redacted]
3.1.2.1 The appendix 3 identified the incorrect sponsor company.
3.1.2.2 The trial details were not identified in the document.
3.1.2.3 The sponsor details for complaints were not identified.
3.1.3 There were a number of signatures missing from the IMP Project Overview record for [redacted]

Reference: EU GMP C4.2, C4.8, Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use 6.4

3.2 **The deviation process and procedure were deficient, as evidenced by;**
3.2.1 The risk assessment process used to classify deviations allowed 'Critical' severity incidents (that had actually occurred) to be classed as 'Major' deviations, if they were considered unlikely to have happened, or easily detectable. Additionally, 'Major' severity incidents could be classed as 'Minor' deviations for the same reasons.
3.2.2 Deviation [redacted] had not been recorded in batch record [redacted] This deviation was therefore not identified during batch certification and not communicated to the customer.
3.2.3 The investigation timeline extension to deviation [redacted] (and associated CAPA) had not being raised in a timely manner.
3.2.4 Despite the certain customers requiring notification within one day of a deviation being identified, the proceduralised timeline to raise a deviation was two working days after being identified.
3.2.5 The timelines for effectiveness checks were not related to the frequency that the activity occurred. The timelines for evaluation were stated as being required to be no earlier than 3 months, and not later than 6 months.
3.2.6 The deviation SOP did not require consideration of a recall when a Critical deviation was raised.

Reference: EU GMP C1.4(xiv), C1.13, Detailed Commission guidelines on good manufacturing practice for investigational 5.5

3.3 **The qualification process was deficient, as evidenced by the HPLC documentation:**

3.3.1 The IQ/OQ had been carried out in October 2023, however the DQ had not been carried out until January 2024 (this was a repeat finding from the previous inspection).

3.3.2 The IQ/OQ was provided by the supplier and had not been pre-approved by Eramol.

3.3.3 The URS for the HPLC lacked specific checks e.g. on specific expectations from Annex [redacted]

Reference: EU GMP A15.2.6, A15.2.10, A15.3.2,

3.4 **The cleaning validation SOP was deficient as evidenced by a number of invalid statements, incorrect weighting of risks, and detail that did not reflect the actual operations carried out at site.**

Reference EU GMP C4.2

3.5 **The commercial batch certification [redacted] did not provide a clear description of the circumstances under which a deviation would / would not impact upon the QPs ability to certify a batch.**

Reference: EU GMP A16.3

3.6 **The OOS/OOT process and procedure were deficient, as evidenced by:**

3.6.1 The investigation of [redacted] incorrectly identified the root cause of [redacted] as 'unavoidable particulates'. Although this was communicated as the root cause by the supplier of the excipient, this was not conserved to be justifiable. Additionally, there was no documented consideration of the suitability of other batches received from the same supplier.

3.6.2 There was no consideration of the early pulling of the next stability sample after an OOT was identified that had no identified root cause.

Reference: EU GMP C1.4(xiv), C6.35

3.7 **The control of materials was deficient, as evidenced by;**

3.7.1 The confirmation that APIs received had not been adulterated could not be assured, as there was no procedural requirement to confirm the seal numbers or seal design.

3.7.2 The walk-in cold store at [redacted] (Gatwick) was overloaded.

3.7.3 Materials in the [redacted] walk-in cold store were being stored on their side despite signage indicating they were to be stored upright.

3.7.4 It could not be assured that empty capsules were being stored in the required humidity conditions in unit 9 (Sevenoaks).

Reference: EU GMP C3.18, C3.19

3.8 **The complaints SOP did not require the sample to be obtained to aid the investigation. Additionally, there was no requirement to consider a recall in the event of a critical complaint being received.**

Reference: EU GMP C8.9(iii), C8.9(v)

3.9 **The definition of a 'temporary change control' allowed changes to be made outside of registered parameters without notification to the regulatory authority.**

Reference: EU GMP C1 Principle

4 COMMENTS

4.1 The site were requested to provide an update to the inspectors on the action to implement a new training system at the time of the action completion (target date 31st March 2024), and a subsequent update on the effectiveness of the change (at the defined effectiveness date recorded in the PQS). Any delays in the completion of the activity should be communicated.

4.2 The site committed to review their current licences and submit variations to correct any anomalies identified. The intent of the MIA license was discussed and the site confirmed they would review this licence and communicate any updates to the MHRA.

4.3 It was noted that the SMF for the Gatwick site was not up to date, and the site committed to update this document.