



Medicines & Healthcare products
Regulatory Agency



MHRA

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RESTRICTED – COMMERCIAL

[REDACTED]
GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED
COBDEN STREET
MONTROSE
DD10 8EA
UNITED KINGDOM

Date 05/09/2022

Case No: Insp GMP 4/117769-0022

SUBJECT: THE HUMAN MEDICINES REGULATIONS 2012 (as amended) (SI 2012/1916)

AUTHORISATION / REGISTRATION NO. API 4

Dear [REDACTED],

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 31/08/2022.

During the inspection a number of failures to comply with the principles and guidelines of Good Manufacturing Practice and / or Good Distribution Practice were observed and these are listed in the Appendix to this letter.

Please reply within 28 days, giving your proposals for dealing with these matters, together with a timetable for their implementation. Please send your response electronically by e-mail to me at the email address below.

It would be appreciated if your response was in the following format:

1. Restate the deficiency number and the deficiency as written below.
2. State the proposed corrective action and the target date for completion of these action(s)
3. Include any comment that the company considers appropriate.
4. Please provide the response as a word document.

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Inspection Date: 31/08/2022

Company: GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED,
MONTROSE

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Further guidance on responding to inspection deficiencies can be found at the following web link <https://www.gov.uk/guidance/guidance-on-responding-to-a-gmpgdp-post-inspection-letter>

Yours sincerely


GMP Inspector

E-mail: 

**FAILURES TO COMPLY WITH THE GUIDE TO GOOD MANUFACTURING /
DISTRIBUTION PRACTICE**

1. **CRITICAL**

None

2. **MAJOR**

None

3. **OTHER**

- 3.1 The recording of dispensary activities required improvement, as evidenced by:
- 3.1.1 Not all activities were recorded at the time they were performed (it is acknowledged that the site were planning to introduce electronic batch records at some point in the future):
- 3.1.1.1 Dispensed weights were not completed contemporaneously and were only captured post-dispensing once the operators had exited the sampling booth and de-gowned. The inspector observed that 18 separate weighings of an API had been dispensed but not recorded.
- 3.1.1.2 Balance calibration data was not completed contemporaneously. Although the balances were subject to a multi-point check prior to commencing dispensing operations, the results were not recorded until after the completion of the dispensing activities.
- 3.1.2 Balance calibration data was only recorded to 2 decimal places, whereas the balance was capable of reading to 3dp and the stated tolerance was to 3dp.
- EU GMP Part II 2.15, 6.14
- 3.2 QC operations were deficient, in that:
- 3.2.1 Although OOS [REDACTED] was related to 12 batches of [REDACTED] that had been tested together, only the 4 OOS batches had been subject to retesting once the root cause was determined to be related to sample preparation.
- 3.2.2 The chain of custody of refrigerated and frozen samples provided to QC was not adequately recorded to identify the total time spent out of cold storage.
- 3.2.3 The risks of not performing temperature mapping of the reference standards refrigerator in QC had not been adequately considered.
- 3.2.4 Procedure LSOP [REDACTED] was not followed for stability chamber temperature mapping. For example, only a 2-hour temperature map at PQ ([REDACTED]) was described for the chamber conditions that potentially may not have adequately assessed the performance of the equipment at in-use conditions (it is acknowledged that the site

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	described that further temperature mapping of the chamber was planned).
EU GMP Part II	2.12, 2.21, 6.61, 11.15
3.3	Equipment labelling was inconsistent, as evidenced by:
3.3.1	Not all pipework lines were clearly labelled with the direction of flow. For example, the purified water and CIP lines on vessel [REDACTED] in building B67N.
EU GMP Part II	4.23
3.4	Equipment calibration was deficient, as evidenced by:
3.4.1	The temperature probe in the cold store ([REDACTED]) had not been calibrated since 2019, despite having a 12-month calibration frequency. Although there was a note acknowledging the missed 2021 calibration, there was no documented record of why the 2020 calibration had been missed.
3.4.2	It was confirmed that other temperature probes were similarly lacking in recent calibrations.
EU GMP Part II	5.30

4. COMMENT

None