



MHRA

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RESTRICTED - COMMERCIAL

STERLING PHARMA SOLUTIONS LIMITED DUDLEY LANE DUDLEY CRAMLINGTON NE23 7QG UNITED KINGDOM

Date 08/01/2024

Case No: Insp GMP 29350/292119-0006

SUBJECT: AUTHORISATION / REGISTRATION NO.

Dear

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 09/06/2021.

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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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:

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

1. CRITICAL

None

2. MAJOR

None

3. OTHER

None

4. **COMMENT**

None