



Medicines & Healthcare products  
Regulatory Agency



**MHRA**

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United Kingdom

[gov.uk/mhra](https://gov.uk/mhra)

RESTRICTED – COMMERCIAL  
[REDACTED]

[REDACTED]  
PROCTER & GAMBLE (HEALTH & BEAUTY CARE) LIMITED  
PIMBO ROAD  
WEST PIMBO  
SKELMERSDALE  
WN8 9PE

Date 15/09/2022

Case No: Insp GMP/GDP 129/3462-0011

**SUBJECT: THE HUMAN MEDICINES REGULATIONS 2012 (as amended) (SI 2012/1916)AUTHORISATION / REGISTRATION NO. 16098**

Dear [REDACTED],

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 13-14 Sept 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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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/GDP Inspector

E-mail: 

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

**1. CRITICAL**

None

**2. MAJOR**

- 2.1 [REDACTED] had been released to market out of compliance with the Marketing Authorisation as detailed in [REDACTED] raised on the [REDACTED] without DMRC being informed. The lead limited for the talc being greater than in the registered specification.

EU GMP Chapter 8 Principle

- 2.2 There was no production manager named on MIA 16098 and the assumed individual's job description did not contain details pertaining to his responsibilities in his role as production manager indicating a failure in change management.

EU GMP C1.4(xii)

**3. OTHER**

- 3.1 Quality Management systems:
- 3.1.1 Product Quality Reviews for [REDACTED] products for January 2020 to December 2021 that the Skelmersdale site was responsible for had not been completed at the time of the inspection. There was no timescale defined in the [REDACTED]
- 3.1.2 Deviation management:
- 3.1.2.1 [REDACTED] – a half filled bottle of [REDACTED] raised in May 2021 contained contradictory statements that the QP had been informed and later that he had not and it was not clear that all the actions on the action list had been completed.
- 3.1.2.2 [REDACTED] – lack of validation of rework of [REDACTED] involving more than 1 pass through the heat tunnel on the packing line had no product impact assessment.
- 3.1.3 CAPA Management:
- 3.1.4 CAPAs had not been followed up for the self-inspection of validation and change management for June 2021. (The actions created were sometimes not appropriate as they for example involved a subsequent review.)
- 3.1.5 There had been no 'out of hours' mock recall. This deficiency had been raised in relation to the [REDACTED] at a previous MHRA

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inspection in 2016.

EU GMP C1.4(viii), C1.4(xiv), C8.30

3.2 Documentation:

3.2.1 A consolidated VMP in line with Annex 15 was not available for site and not all equipment and qualification activities were included in the spreadsheet associated with qualification activities at site for example of computer systems and area qualification.

3.2.2 There was uncontrolled documentation in the GMP production area.

EU GMP Chapter 4 Principle, A15.1.5(i-vii)

3.3 The Quality Technical Agreement between [REDACTED] and [REDACTED] was deficient as follows:

3.3.1 It was not clear who was responsible for carrying out the excipient risk assessment.

3.3.2 It does not detail recall responsibilities.

3.3.3 Point 20 refers to release and not certification and release.

EU GMP C7.15

3.4 TSE statements did not detail processing aids for example the statement for [REDACTED] packaging materials stated that the finished product did not contain any material of animal origin but did not mention processing aides.

Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3)

3.5 Equipment and facilities:

3.5.1 It was not clear whether calibration records from the temperature monitoring probes used for the facility had been reviewed or understood.

3.5.2 There was no temperature probe in the sample retain storage area.

EU GMP C1.4(vii), C3.19

4. COMMENT

4.1 Please confirm that the manufacturers in the USA and Mexico are applying a toxicological approach to cross contamination for shared facilities for products being imported as necessary.

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4.2

Please inform the MHRA when supply of [REDACTED] products recommences.