Medicines & Healthcare products Regulatory Agency

INSPECTION REPORT

Tillomed Laboratories Limited
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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Routine Re-Inspection

Licence or Reference Number: MIA / WDA(H) 11311

Licence Holder/Applicant: Tillomed Laboratories Limited

Details of Product(s)/ Clinical trials/Studies: Importation and wholesale dealing. Tillomed products include sterile (aseptically formulated and terminally sterilised) liquid formulations and lyophilised products and non sterile products (tablets and capsules)

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	N
Manufacture of Finished Medicinal Products - Biologicals	N
Manufacture of Intermediate or Bulk	N
Packaging – Primary	N
Packaging - Secondary	N
Importing	Y
Laboratory Testing	N
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other: *Wholesaling*	Y

Name and Address of site(s) inspected (if different to cover):
Site Contact: [redacted]

[redacted]

Date(s) of Inspection: 9-10 September 2025

Lead Inspector: [redacted]

Accompanying Inspector(s): [redacted]

Case Folder References: Insp GMP/GDP 11311/16282866-0008

Section B General Introduction

B1 Background information

Tillomed is a virtual importer and wholesale distributor who imported product from both third countries and the EU. Tillomed is a wholly owned subsidiary of Emcure Pharmaceuticals Limited, a global company with its headquarters in India. It adopted a [redacted] in 2017. There are [redacted] CMOs and the product range includes both sterile and non-sterile products. The MIA has been held since 2002 and the WDA(H) since 1996.

Imports are from [redacted]

Supplies are to the [redacted]

Testing labs include: [redacted] (There was a change control in progress to remove [redacted] from the licence as a testing site).

Contract wholesalers include [redacted]

[redacted] and [redacted] are used as contract packaging sites.

Until last year the company operated with the [redacted] but since the last inspection the latter no longer holds an MIA or a WDA(H).

The last inspection in 2022 identified some major issues and a Type 2 post inspection letter was issued.

Export had been limited.

[redacted] mainly supplied the EU market.

Tillomed do not supply directly to the [redacted] but to other wholesale dealers eg [redacted]

Previous Inspection Date(s): 12-13 Sept 2022

Previous Inspectors: [redacted]

B2 Inspected Areas

Quality Management Systems: Quality Management review, Product Quality Reviews, Deviations, CAPA, Change Controls, Complaints, Recall, Outsourced activities, Training, Artwork Control, Batch certification, PQRs, Management Review, Supply chain maps, Supplier and Customer qualification, Suspicious transactions, Returns, Batch certification and release

Limitations / exclusions to inspected areas

Computer validation may be of interest at the next inspection, and the site is increasing the use of electronic systems.

B3 Key Personnel met/contacted during the inspection

Name	Job Title

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

B4 Documents submitted prior to the inspection

Document	Version /Date of document	Reflected activities on site?
Site Master File	Version [redacted] Dated Aug2025	Y
Compliance Report	Dated 1st Sept 2025	Y
Comments: Documents reflected site activities.		

Section C Inspector's Findings

C1 Summary of significant changes

Detailed changes are recorded in the pre-inspection compliance reports held in the case folder.

Changes since previous inspection which are of particular relevance to compliance / risk rating, or which relate to inspection deficiencies are listed below:

[redacted] MIA and WDA(H) cancelled.

Trend towards use of digital systems eg [redacted] (QMS), [redacted] (Training), batch release system and artwork control system.

New storage site [redacted]

QC Labs: [redacted] was in the process of being removed from the licence (see change control section below)

New CEO, QA Manager and Assistant QA manager. 3 staff left the company

Increase in headcount to 23. Majority of which are located in India

Future planned changes which are of particular relevance to compliance / risk rating, or which relate to inspection deficiencies are listed below:

Ongoing digitalisation of QMS such as e logs and vendor management system.

[redacted]

C2 Action taken since the last inspection

There had been a significant increase in Quality staff since the last inspection and oversight appeared to have improved. There was no major deviation for this inspection.

Actions reviewed during inspection- no issues.

C3 Starting Materials

General

Supplier approval is governed by SOP [redacted] CMOs and labs are audited by the QPs. API audits are carried out by qualified auditors from the corporate team. An annual audit schedule was in place. It covered third party audits and for cause audits and remote desktop audits although the latter had not been carried out recently. Disqualification is covered in the case of critical findings.

The audit of [redacted] the manufacturer [redacted] was This audit had been carried out by [redacted] a contract audit company on the 23-24 March 2023. The CAPA report was available however the QP review was not documented.

The audit of the CMO for [redacted] was reviewed. This was the newest product to be added be onboarded. 1 batch had been imported at the time of the inspection. The audit was carried out over 3 days in November 2023.

The audit of [redacted] the suppliers of [redacted] was reviewed.

Compliance with TSE Guidelines

TSE Compliance was managed through procedure SOP [redacted] Rev [redacted] The company maintained a log for all products with links to the corresponding API and BSE/TSE certification was available. This noted both the issue and expiry date with a three-year review period. An example product was reviewed, and a BSE certificate was provided for both the product and API and were appropriate and within expiry.

BSE/TSE review also formed part of the PQR review as evidenced in PQR [redacted] with reference to the TSE compliance of [redacted]

API Compliance

The audit of the API supplier [redacted] carried out by [redacted] n June 2024 was examined. CVs of auditors were available. Again, there was no documented review by the QPs.

C4 Pharmaceutical Quality System

Quality Management Reviews

SOP [redacted] Rev [redacted] described the process for Quality Management Reviews and meetings were required on a quarterly basis as a minimum. The minutes and slides from Apr-Jun 2025 were reviewed. The minutes from Jan-Mar2025 were also reviewed and no issues were noted.

The management review for Apr – Jun 2025 showed that [redacted] QP declarations had been signed within the quarter. There was no procedure or training to support this activity within Tillomed. (see deficiencies)

Product Quality Reviews

PQRs are governed by SOP [redacted] Rev [redacted] This stated that where a small (statistically invalid) number of batches (Less than 5) of a product have been manufactured in the year then review

of these batches will be carried out in next review period, which contradicted the requirement for an annual review. See deficiencies

They are prepared by the CMO and reviewed by Tillomed UK. A schedule was in place maintained on an [redacted] spreadsheet. There was a timeline of 120 days for sign off following the period of review. A comparative review of testing results was referenced. The QP approves the PQR. Where QP release is by a 3rd party it will be their responsibility to generate the PQR with copies provided to the MAH Tillomed laboratories UK.

Deviations

The deviations SOP [redacted] Rev [redacted]

Issues with artwork and outdated PILs had been the cause for BSVs and some of which had been refused.

The following deviations were reviewed.

[redacted] – [redacted] packaged with the out-of-date leaflet. 2 batches had been released by the QP before a QA reviewer identified that the PIL was out of date. This was linked to a change control where actions had not been completed on time. Other products had not been considered. A root cause analysis had been carried out. CAPAs and preventive actions were in place including blocking of the [redacted] code at the CMO and an enhanced QA review in [redacted] relating to artwork and the QP batch review checklist. An artwork tracker was in place.

CAPA [redacted] had been raised and included actions for a formal notification to the CMO. Cut off dates for the use of old artwork the [redacted] blocking of artwork codes. The CAPA was not closed at the time of the inspection, but procedures were in place and being rolled out. Regulatory sign off the Batch Packaging Record (BPR). This is an action on an associated change control. The updated BPR for the above was in place.

[redacted] – lack of release testing for [redacted] from [redacted] Had been released on the basis of bulk testing results in error. DMRC were informed and retrospective testing of the retain was carried out. No market action was taken. The 5 whys had been used as part of the investigation. Appropriate CAPAs were in place including a procedural amendment and a block in the system until an EU C of A became available.

CAPA [redacted] had been raised for the actions required as a result of the above deviation. The procedure [redacted] Rev [redacted] [redacted] had been updated. Training records for the QA reviewers were checked. There were 4 reviewers based in [redacted]

[redacted] – Batch of [redacted] released with out-of-date PIL. The discrepancy related to the [redacted] which had changed an ingredient. DMRC were informed but no market action was taken. CAPAs had been put in place but the more recent deviation in the same area had meant further additional actions were required.

[redacted] concerning [redacted] artwork [redacted] where 2 strengths had been printed on the carton which detailed [redacted] on one of the side panels of the carton. This product was manufactured in [redacted] and no batches had been certified in the UK. This was identified at [redacted] and had not been pick up during regulatory or MHRA review. An automated artwork system had been put in place comparing the previous version with the new artwork. The error had occurred and been introduced during an update.

[redacted] This was a temperature excursion. Low temperature however this was identified to be a faulty data logger. 2 data loggers had abruptly stopped recording. There was also a minor excursion. This product was being transported by air freight. The CMO in [redacted] had been informed regarding the data loggers. A deficiency was raised due to a lack of detail in the records.

[redacted] a temperature excursion for [redacted] from [redacted] for the [redacted] Market. Some of the loggers showed significant deviation up to 50°C An additional stability

study had been carried out at [redacted] which supported the decision to release some of the batch. Part of the batch had been rejected, that which had exceeded 50°C. Records of this were available. A CAPA was in place to avoid further excursions of this nature. These included use of thermal blankets for air freight, avoiding daytime flights, etc,

There was an SOP for [redacted] Rev [redacted] and a site risk log.

The following risk assessment reports were reviewed

[redacted] – This was a risk assessment for the continued supply of [redacted] following an FDA inspection which resulted in batch certification being stopped until the risk assessment was complete. A redacted copy of the FDA report was available. Audits had been carried out, both by the MAHs and an independent audit.

Issues with [redacted] released with out-of-date leaflets. This is a recent issue for which BSVs have been submitted and refused. The product batches are currently being repackaged with the most up to date leaflet. The respective MAs have been varied to reflect the addition of [redacted] as a packaging site. CAPAs in place to prevent this happening again appeared to be appropriate but have only recently been introduced and therefore their effectiveness could not be fully assessed at this inspection. The CAPAs were deemed appropriate as detailed in records for [redacted]

Issues with [redacted] were discussed with the company. Changes to formulation identified by the assessor were discussed. It was described as a tightening of the spec as the registered details contained a statement [redacted] for the [redacted] However, the company state that this quantity has never been used. In fact, a target of [redacted] and then [redacted] are used. This product had been QP certified at the [redacted] CMO site and RPi released by Tillomed.

The company had raised change controls ([redacted]) when they submitted batch specific variations related to the [redacted]

The company had taken actions such has ceasing QP certification whilst the discussions with the assessor were ongoing and worked with the DMRC regarding released batches. These were not captured formally within the quality system as CAPAs. The wider implications to other legacy dossiers had not been assessed. See deficiencies.

The change control for the introduction of the new product [redacted] was reviewed

<u>Change Controls</u>

The Change Control procedure was [redacted] Rev [redacted] No issues were noted.

The change control log was reviewed and this showed that a number of change controls were initiated in the system and had not been had an initial quality review for extended periods of time ranging up to 6 months. For example (6 months since logging in system) [redacted] (4 months since logging in system) [redacted] These were not reviewed at the quality management review in terms of progress or if the risk of delay had any impact. A total of 48 records were in this initial state in the log of change controls sent to the inspectors. See deficiencies.

[redacted] – Addition of a new secondary packaging and storage site. The record had been extended twice. The system required a justification for the extension and this had been provided. No issues noted.

[redacted] – addition of [redacted] as physical importation, storage and distribution site. This change was still in the process of being implemented. No issues noted.

[redacted] - Repackaging of [redacted] with correct PIL. No issues noted.

[redacted] was initiated on 21 Aug 2025 to remove[redacted] as a QC testing site. This record was in progress so the licence hadn't been updated to reflect it yet. There was an action in the record to cover this. No issues noted.

[redacted] - the termination of contract for storage with[redacted] which was completed in 2024, did not consider their removal from the WDA(H) licence. The contract storage site was still named on the licence at the time of the inspection. See deficiencies

[redacted] were reviewed as part of the data package relating to the issues related to[redacted] detailed in the deviation section. No change control specific issues noted.

Batch Certification

Batch release and certification was managed under SOP[redacted] Rev[redacted] and this allowed for both onsite or remote certification. There was evidence of both methods of certification occurring. All records were held electronically which allowed the QP access. The release procedure allowed for a QP to change disposition status and upon discussion the intent was for this to be from release to reject only. The wording within the procedure also allowed for a disposition change from reject to release. See deficiencies.

The company had introduced an electronic batch release system[redacted] and this was reviewed. The software qualification[redacted] was reviewed and this showed that QA, RP, RPi and QP had discrete activities within the system which they had access to, to enable them to do their role. The system access was demonstrated by a QA colleague, and they did not have access to the QP release functions. No issues noted.

The QP demonstrated the certification process for 2 batches[redacted] 29 July 2024 and[redacted] and the systems in place that allow the QP access to the appropriate documentation including batch records, packaging batch records, testing results (import and release), QP samples (photos of the final pack) and the current filing.

The product specific risk assessment for[redacted] was reviewed and this showed that the samples were required to be shipped in advance of commercial stock shipment due to an increase in an impurity ([redacted]). The company described this as due to an aging factor. The specifications for both release and stability were reviewed and showed[redacted] content by ion chromatography as[redacted] respectively. The company had evidence of submitting a variation to the[redacted] regulator to adjust the release specification which was subsequently not approved, hence this process.

C5 Personnel

There were 23 QA staff employed by the company. This is an increase of 64% since the last inspection. The training records of 4 QA reviewers who were responsible for the QA review of batch documentation were reviewed with respect to an update in an associated[redacted] These 4 staff were located in[redacted] and one representative attended the inspection.

There were 8 staff located at the Luton office.

The licence has 4 QPs listed[redacted] The remaining three, 1 was an FTE (and had multiple roles within the company), and 2 were contractors (1 for 4 days/week and one 2 -3 days /week depending on need).

Training was managed under SOP [redacted] Rev[redacted] and supported by an electronic system (this was a recent change).

The 2024 annual GMP/GDP training was provided by a consultant, and their CV was available and appropriate. The training covered basic GMP principles and had a specific annual focus area regarding the Windsor framework. The associated test for this training for a colleague was reviewed and this showed 10 questions and was marked by the consultant and resulted in issuance of a certificate. A log was in place and managed to ensure all staff received the training.

The QP certification SOP indicated that to certify products within Tillomed a colleague was required to be a QP and did not include any specific requirements for onboarding a new QP and associated training/familiarisation required to enable certification of Tillomed products and dosage forms. See deficiencies

The electronic training system was reviewed. No issues noted

The training and qualification process for QA Personnel in Batch manufacturing documentation was reviewed and no issues were noted.

The training for a contract QP was reviewed and issues regarding no training for QP declarations and no initial training for familiarisation with Tillomed products were noted. See deficiencies.

C6 Premises and Equipment

N/A this was a virtual company

C7 Documentation

There were some inconsistencies with SOPs noted. See deficencies.

C8 Production

N/A this was a virtual company

C9 Quality Control

Finished product testing was carried out at either a UK lab or the [redacted] lab in [redacted]

AMT and method transfer records for [redacted] was reviewed. The validation of the micro testing was available. Each batch is tested for micro.

The technical Director QA gets copies all OOSs both from the CMOs and the contract laboratories. For contract testing laboratories only the summary reports are provided. Trends are carried out.

C10 Outsourced Activities

[redacted] had been approved to assist with artwork control. The company have been approved for setting up the plates with information provided by Tillomed. They do not carry out any translation and all plates are checked by the artwork controller in the UK prior to submission.

[redacted] a contract lab had been audited in 2003 by Tillomed staff. 1 day 2 major and 6 other deficiencies were identified. It had covered data integrity. There was not a large amount of detail on the management of OOS and a significant number of recent OOSs were attributed to analyst error.

The QTA with [redacted] had a section referring to unlicensed medicines which is not an activity Tillomed are licensed for (See deficiencies)

In the 2025 audit report for contract laboratory [redacted] the risk rating for reinspection was completed prior to receipt and acceptance of the contractor responses to the deficiencies. There was no subsequent company review once the responses were received and accepted to indicate whether the risk rating remained unchanged. See deficiencies.

C11 Complaints and Product Recall

Recalls were managed under SOP [redacted] Rev [redacted]

In 2024, there was a Class 2 recall for [redacted] (batch [redacted]) due to a potential mix up during secondary packaging. (Reference [redacted]). This product was manufactured at [redacted] a contract manufacturer and the company triggered a 'For cause' inspection at the manufacturer site in May 2025. There was no assessment of risk for the time period and products manufactured by this company were still releasable. See deficiencies. The inspection was conducted by a [redacted] QP and a CV was available. A CAPA plan and implementation dates to support the inspection were available.

In 2022, a mock recall was performed on [redacted] It was initiated during the working day and the report had a product reconciliation. There were some actions noted from the mock recall and these were raised as formal CAPA. No issues noted

To show that the recall process had been tested out of hours, the 2023 Class 2 recall for [redacted] This showed that the recall process had commenced out of business hours and no issues were noted (Reference [redacted])

Customer complaints were managed under SOP [redacted] The customer complaint trend analysis for 2024 was reviewed. The log provided to the inspectors pre-inspection was missing data from Sep – Dec 2024. This was noted during the inspection and was due to an error compiling the data which was between 2 systems.

Complaint [redacted] was reviewed and no issues noted.

Complaint [redacted] was reviewed which had an initial risk category of critical. It had a suitable investigation report and the company had followed up with PV actions- no issues noted.

C12 Self Inspection

Self Inspection- a schedule was in place. The inspection for RP duties was reviewed.

C13 Distribution and shipment (including WDA activities if relevant)

There was an SOP for unusual sales patterns in place. There was a lack of overall transport risk assessment for transport routes from 3rd countries to the UK.

There was a QTA in place between Tillomed UK and [redacted] [redacted] carry out sampling, photographed QP samples and kept retains for Tillomed. Returns were handled by the Tillomed RP

Tillomed carry our all other RP duties such as returns, Bonafide checks.

A comprehensive review of sales patterns was carried out by the RPs.

Several checks were made of the bone fide status of suppliers and customers eg [redacted] including export customers. All were found to be in order, and the annual review was controlled via [redacted] which blocked the account and prevented orders if the review was overdue.

Checks were also carried out on the export ban list and the lists of suspended WDA(H) licenses on the MHRA website were reviewed regularly.

RPi checks were carried out by one of the QPs and records were examined,

Returns were managed under SOP [redacted] Rev [redacted] This had a section which referred to unlicensed medicines which is not an activity Tillomed is licensed for. (see deficiencies) Records of returns were examined and found to be in order.

C14 Questions raised by the Assessors in relation to the assessment of a marketing authorisation

N/A

C15 Annexes attached

Annex 1 site risk rating

Section D List of Deficiencies

1 CRITICAL

None

2 MAJOR

None

3 OTHERS

3.1 Quality Management Systems were deficient in that:

3.1.1 **Management of deviations**

3.1.1.1 Deviation [redacted] packaged and released with the out-of-date leaflet lacked a wider review of other products to see if they were affected by the lack of robust systems in place at the time the deviation occurred.

3.1.1.2 [redacted] a temperature deviation for [redacted] imported from [redacted] did not contain communications and associated CAPAs with the CMO regarding the temperature data loggers, 2 of which were thought to be faulty.

3.1.2 **Change controls**

3.1.2.1 The prospective evaluation of planned changes did not fully evaluate all the actions required for implementation as [redacted] -the termination of contract for storage with [redacted] did not consider their removal from the WDA(H) licence. This change control was completed in 2024 and the contract storage site was still named on the licence at the time of the inspection.

Reference: ***EU GMP C1.4 (xii), C 1.4 (xiv) C1.8 (vii) C 4 principle***

3.2 Risk management controls were inadequate in that:

3.2.1 Change controls were initiated in the system and had not been had an initial quality review for extended periods of time ranging up to 6 months. For example (6 months since logging in system) [redacted] (4 months since logging in system) [redacted]

[redacted] These were not reviewed at the quality management review in terms of progress or if the risk of delay had any impact. A total of 48 records were in this initial state in the log of change controls sent to the inspectors.

3.2.2 In the [redacted] 2025 inspection report, the risk rating for reinspection was completed prior to receipt and acceptance of the contractor responses to the deficiencies. There was no subsequent company review once the responses were received and accepted to indicate whether the risk rating remained unchanged.

3.2.3 There was a 2024 recall for product manufactured at [redacted] in Oct 2024 which triggered a 'For cause' inspection at the manufacturing site in May 2025. There was no assessment of risk for this time period and products manufactured by this contractor continued to be released by the company.

3.2.4 A formal transport risk assessment had not been carried out for transport from outside the UK to the third-party logistics provider.

Reference: EU GMP C1.13 (i), 1.13 (ii), Annex 15 6.3, GDP 9.2

3.3 Documentation and Procedures were inaccurate, ambiguous and lacked detail. For example,

3.3.1 SOP [redacted] stated that where a small (statistically invalid) number of batches (Less than 5) of a product have been manufactured in the year then review of these batches will be carried out in next review period, which contradicted the requirement for an annual review.

3.3.2 SOP [redacted]

3.3.2.1 Allowed for a QP to change disposition decision. This also allowed for a change from reject disposition to release disposition.

3.3.2.2 Had no reference to Tillomed specific requirements for onboarding a new QP and associated training/familiarisation required to enable certification of Tillomed products and dosage forms.

3.3.3 QP declarations had been completed in 2024 as evidenced by the 2024 management review slides. There was no procedure nor training associated with this activity.

3.3.4 SOP [redacted] Returned Goods procedure and the QTA with [redacted] both referred to unlicensed medicinal products and Tillomed are not licensed for unlicensed medicinal products

3.3.5 There were no transport routes detailed in the API supply chain reviews.

Reference: EU GMP, C1.8(iv) C1.10(i), C2.11, C 4 Principle C4.3, Annex 16 1.2.

3.4 There was no formal quality system documentation relating to all activities completed relating to the differences Tillomed noted between the [redacted] dossier and formulation. The company had completed some mitigating actions and these were not formally captured as CAPAs and the wider implications to other legacy dossiers had not been assessed.

Reference: EU GMP C1.4 (xiv) (ii) (viii) C4 Principle C4.8

3.5 Supplier Approval processes were deficient in that

3.5.1 There was currently no documentation of the 3rd party audit review by the QP as evidenced by the audits of [redacted] for example [redacted] the CMO for [redacted]

3.5.2 The audit report for [redacted] was weak on narrative regarding data integrity and compliance with the MA.

3.5.3 The audit of [redacted] limited the manufacturer of [redacted] did not contain details on cross contamination PDE and associated controls.

Reference: C1.4 (vii), C7.2, EU GMP Annex 16 2.2(iii), 2.2(iv)

4 COMMENTS

None

Section E Site Oversight Mechanism

Site referred or to be monitored by:	Tick (✓)	Referral date	Summary of basis for action
Risk Based Inspection Programme	✓	[redacted]	[redacted]
Compliance Management Team			
Inspection Action Group			

Section F Summary and Evaluation

F1 Closing Meeting

All responses were verbally accepted at the closing meeting.

F2 Assessment of response(s) to inspection report

The Post inspection letter was sent on 16 Sep 2025 and a response was received on 11 Oct 2025. These responses were reviewed and accepted.

F3 Documents or Samples taken

None

F4 Final Conclusion/Recommendation, Comments and Evaluation of Compliance with GMP and GDP

The site operates in general compliance with the requirements of:

Compliance statement	Tick all statements that apply
GMP as required by the Human Medicines Regulations 2012 (as amended) and the Human Medicines (Amendment) Regulations 2019	✓
The Medicines for Human Use (Clinical Trials) Regulations 2004	

Regulation 5 of the current Veterinary Medicines Regulations	
Regulation C17 of the Human Medicines Regulations 2012 (as amended) and the Human Medicines (Amendment) Regulations 2019	✓

and is acceptable for the products in question.

Name of Inspector (s):

Lead Inspector: [redacted] **Date: 13 October 2025**

Accompanying Inspector: [redacted] **Date: 13 October 2025**

Annex 1

GMP Site Risk Rating

(a). Inspection Findings

Critical deficiencies this inspection:	0	Last inspection:	0
Major deficiencies this inspection:	0	Last inspection:	5
Other deficiencies this inspection:	5	Last Inspection:	1

(b). Provisional Rating based on Inspection Output (✓ applicable box)

Risk rating level	Input from current Inspection Findings (last inspection findings applicable to rating V only)	Provisional rating – this assessment	Final rating last assessment
0	Serious triggers outside the inspection cycle	[redacted]	
I	Critical finding		
II	>/= 6 Major findings		
III	<6 Major findings		
IV	No critical or Major findings		
V	No critical or Major findings from current or previous inspection and <6 other findings on each.		

(c). Risk Assessment Inputs – discriminatory factors (✓applicable box)

[redacted]	None relevant (default)
	Significant concern over robustness of quality system to retain adequate control
	Significant failures to complete actions to close previous deficiencies raised at the last inspection
	Complex site
	Significant changes reported in Compliance Report
	Significant mitigating factors applied by the site
	Higher risk rating identified by other GxP and considered relevant to the GMP site
	Relevant site cause recalls, notifications to DMRC or rapid alerts since last inspection
	Nature of batch specific variations submitted since the last inspection give concern over the level of control
	Regulatory action related to the site
	Failure to submit interim update and/or failure to notify MHRA of significant change or slippage in commitments from post inspection action plan
	First Inspection by MHRA (does not require counter-signature for RR II)
	Other discriminatory factor (record details and justify below)

(d). Inspectors Comments Related to Discriminatory Factors

[redacted]

(e). Risk Rating Result Incorporating Discriminatory factors (✓ applicable box)

Risk rating level	Inspection Frequency	Inspector Proposed Risk Rating (✓)
0	Immediate (as soon as practicable)	[redacted]
I	6 monthly	
II	12 months	
III	24 months	
IV	30 months	
V	30 months with 50% reduction in duration of the next inspection	

(f). Basis for risk-based acceptance of specific matters arising during the inspection

[redacted]

(g). GMP or GDP certificate conditioning remarks required as a result of risk-based decisions noted in section (f) above

[redacted]

(h). Conclusions

[redacted]

(i). Expert/ Operations Manager / Compliance Management Team (CMT) Comments (Risk rating level 0, I, II): N/A as risk rating is IV

[redacted]

[redacted]

(j). Confirm Agreed Risk rating following this inspection:

Risk Rating:	Next Inspection target date:

[redacted]

Notes regarding re-inspection and GMP certificate validity

1. The inspection schedule is based upon risk and resource. This date may change at any time due to factors not pertaining to your site.
2. The GMP certificate does not 'expire' it is provisionally assigned 3 year validity date. For external questions regarding your validity thereafter; please advise that this can be confirmed by contacting the inspectorate at gmpinspectorate@mhra.gov.uk