



INSPECTION REPORT

ACTIVE PHARMA SUPPLIES LIMITED

UNIT 2

FORWARD INDUSTRIAL ESTATE

TALBOT ROAD

LEYLAND

PR25 2ZJ

UNITED KINGDOM

Head Office:

Inspection, Enforcement & Standards Division, MHRA

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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Routine Re-Inspection (this was the second MHRA inspection)

Licence or Reference Number: API 42785

Licence Holder/Applicant: ACTIVE PHARMA SUPPLIES LIMITED

Details of Product(s)/ Clinical trials/Studies: API Re-packager, Importer/Distributor and exporter
A complete list of all materials and which market they had been sold was available during the inspection. The majority of sales were within the UK.

Activities carried out by company:	Y/N
Manufacture of Active Ingredients	Y*
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	Y
Packaging – Secondary	Y
Importing	N
Laboratory Testing	N
Batch Certification and Batch Release	N
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other: <i>API import, distribution and export</i>	Y

*repackaging and relabelling only

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

ACTIVE PHARMA SUPPLIES LIMITED
UNIT 2, FORWARD INDUSTRIAL ESTATE
TALBOT ROAD
LEYLAND
PR25 2ZJ
UNITED KINGDOM

Site Contact: [REDACTED]

Date(s) of Inspection: 20-21 May 2021 (equivalent to 1 day inspection)

Lead Inspector: [REDACTED]

Accompanying Inspector(s): N/A

Case Folder References: Insp GMP/GDP 42785/13455310-0005

Section B General Introduction

B1 Background information

Active Pharma Supplies Limited (APS) was a privately owned company (established in 2012). The company was set up to import and distribution of APIs, Chemicals and Oils. In January 2015 the business moved to its present location. At the time of the move, two clean rooms were installed to enable repacking of bulk Raw Materials into smaller packs for resale. The company primarily supplied UK based manufacturers of Specials and some materials were exported to EU and outside of the EU.

No materials handled on site that could cause specific harm. [REDACTED] were sold but only as closed packs and they had never been opened and repacked within the site. [REDACTED] were not handled in any way. The site also handled some excipients.

Previous Inspection Date(s): 22nd and 23th November 2016 (1 day)

Previous Inspectors: [REDACTED] (2016)
In Feb 2019 Desktop assessment carried out and GMP certificate extended

B2 Inspected Areas

Deviation, CAPA, Change Control, Management Review, Quality Risk Management, Warehouse, Repackaging, Picking, Supplier Approval, Customer Approval, TSE, Complaints, Recall, Self-Inspection, Calibration, Distribution, Training, Technical Agreements, Document Control, Repackaging records.

Limitations / exclusions to inspected areas

Equipment Qualification, Training records, Pest control

B3 Key Personnel met/contacted during the inspection

Name	Initials	Position
[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	[REDACTED] 19/01/2020	Y/N*
Compliance Report	12/05/2021	Y/N
Comments: * SMF, version [REDACTED] was drafted but not approved at the time of inspection. The version [REDACTED] required several updates, including but not limited to SOP list (incomplete), organigram (new members), frequency of QMS review.		

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:

7 total staff - increase of 3 from 2019 desktop assessment (1 production staff, 1 accounts administrator, 1 salesperson)

QA manager appointed in Jan 2020

No changes in types but increase in amounts of APIs handled. API s that are [REDACTED] were introduced on site and supplied, but without repackaging.

The clean room microbiological monitoring QC is outsourced to [REDACTED]

New QTA with a temperature controlled courier network for when it is required.

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

[REDACTED]

C2 Action taken since the last inspection

The company stated there was no slippages in completing actions arising from the previous inspection.

C3 Starting Materials

General

Suppliers were evaluated according to procedure [REDACTED] – [REDACTED] 24/01/2020. A Quality Questionnaire was sent to a potential new supplier and that the supplier approval process completed before an order was placed. The Approved Supplier List, [REDACTED] was maintained. If the supplier was not the manufacturer, the name of the manufacturer was identified. The written confirmation of GMP standards, from the regulatory authority of the country where the manufacturing site was located was required (if no waiver applicable).

Raw Materials were purchased against agreed specification from an approved supplier.

Auditing of suppliers was performed on a rolling schedule if deemed necessary and suppliers audit reports of manufacturers shared where permissible. Agreements and questionnaires between suppliers and customers were reviewed approximately every 5 years. All audits were paper- based, especially during the Covid-19 pandemic. Future on site audit plans were discussed.

Monthly checks of suppliers' licence status were carried out, to verify if their licence (or any part of their licence) was suspended or revoked or any other non-compliance issues with a company. Suppliers found to have their licence suspended or revoked should be blocked on the [REDACTED] ordering system to prevent purchase order being raised against unapproved suppliers. Investigation through deviations system was required to assess for materials previously purchased from the said supplier.

Examples reviewed included [REDACTED] from [REDACTED] and [REDACTED] active substance where CEP was withdrawn due to Nitrosamine impurities.

Compliance with TSE Guidelines

A TSE statement was required to be obtained from the suppliers and renewal regularly requested according to the TSE risk assessment procedure

API Compliance

See general.

C4 Pharmaceutical Quality System

Quality Management Review

According to the procedure [REDACTED] 24/01/2020, the QMS review was undertaken every three years or opportunistically via an intervention triggered by a CAPA. Information was collated and analysed from the CAPA Database and included Change Controls, Deviations, Complaints, Recalls, and Audits, looking at performance, trends and the effectiveness of corrective and preventive actions implemented. Follow-up actions from previous management reviews should be verified as complete. Any forthcoming changes should be discussed at the meetings. The review will be presented and discussed at company meetings, but there was no quorum determined. Management review meeting minutes must be retained as quality records in accordance with the document control procedure.

The director(s) and managers of APS have six monthly review meetings for updates and feedback on the effectiveness of the QMS. The Quality Manager will present statistics on deviations, customer complaints, recalls and other QMS related issues. CAPA will be discussed and the effectiveness monitored. Due to current situation meetings were held more frequently. The records were reviewed for January 2020 and February 2020, which were regular and triggered by CAPA. The minutes provided detail about discussed topics. However, there were no set agenda which would cover topics as expected according to the relevant procedures; for example, trends for complaints, change controls etc. Although the site stated that the meeting was held in June 2020, there was no record. A deficiency was raised.

Product Quality Review

There was no requirement to carry out PQRs.

Change control

The change controls were covered by the procedure [REDACTED] 24/01/2020. Every change control was evaluated by QA and risk assessment should be performed. The target date assigned should be achievable for all parties involved and it is considered that not more than ninety days from approval of the action plan unless the change control is complex. The procedure was silent about any amendments after the change control implementation started, as well as there was no evaluation of the first batches produced or tested under the change, after the change has been implemented.

The procedure required for change controls to be part of the standard 6 monthly quality review as well as looked at opportunistically based on results of any CAPAs, but this could not be demonstrated by the site. A deficiency was raised.

Several examples were selected for the inspection from the log:

- [REDACTED] – cancelled
- [REDACTED] – [REDACTED] implementation – the change control was updated since the first approval, printed and signed. There was no evaluation of the first batches produced under the change, after the change had been implemented.
- [REDACTED]
- [REDACTED]

- [REDACTED]
- [REDACTED] – new scale printer, still in progress as validation not completed yet.

Deviations

The current procedure was [REDACTED] 24/01/2020 with the relevant forms including [REDACTED] Deviation Reporting Form. A planned deviation was per definition an unexpected event when prevented an SOP from being followed exactly as it was written. This deviation required to be pre-approved by QA and only covered a specific event, time period or batch. All deviations were categorised as minor, major or critical depending on the severity of their impact with a Minor Deviation that did not affect quality in any way, a Major Deviation involved a significant departure from GMP, or written procedures which may affect the quality of raw materials, but would not have an effect on a patient/customer (e.g. temperature out of specification, using a supplier without formal approval) and a Critical Deviation an incident which would cause potential risk or harm to the customer (e.g. using a new supplier without following procedure and without obtaining any GMP documentation or incorrect labelling of an API). Each deviation had to be investigated so that the root cause can be discovered. All deviations were regularly reviewed and analysed for trends. If the deviation happened on a previous occasion, it was investigated as to why the previous preventive action failed.

CAPA

The CAPA procedure was [REDACTED] 24/01/2020. The CAPA Database stored all the data collected from Change Controls, Deviations, Complaints, Investigation Reports, Product Recalls and Internal Audits. Records of completed databases should be kept for at least 5 years. This fixed deadline was discussed with the site to verify how it meets requirements of retention period for records for both, APIs with expiry date and APIs with retest dates.

Quality Risk Management

The [REDACTED] 24/01/2020 procedure was reviewed, and it was of a generic content in line with ICH Q9 guideline. However, risk assessment was incorporated into processes such as complaints. Application of quality risk management was examined on the material-manufacturer case-by-case basis before a purchase was made. This was part of the supplier/ material assessment and considered different available data such as GMP standard, documentation, material complexity, stability etc.

There was no formal risk assessment of contamination and cross-contamination controls which assessed all risks, all areas, processes and measures in place. A deficiency was raised.

C5 Personnel

The company has seven staff (this has increased from at the time of previous 2019 desktop assessment).

The Quality Manager is responsible for training staff or will delegate to a director for some specific types of training. Training per procedure was previously recorded within the procedure, but the site implemented training matrix and training record files. The training matrix denotes which procedures are relevant to the duties of each individual members of staff. A separate one to one training on working in the clean room, GMP and GDP and also practical training for manual handling and equipment used for aiding handling of bulk containers (as per manufacturer's instructions) were required.

C6 Premises and Equipment

The layout is shown in the Site Master File available in the inspection case folder.

The warehouse was accessed via a roller shutter door into a receiving area and then through a single door to the storage areas. New access control system to main warehouse was

implemented. Areas were segregated for released and quarantined stock in the warehouse, fridge and flammable cupboard. Rejected materials were stored in a locked cage which is clearly labelled.

Temperature in the warehouse and cleanroom was controlled by an air conditioning unit and humidity was controlled by a dehumidifier. Temperature and humidity were being monitored by wireless probes. The temperature was controlled between 15 to 25°C. Data from the data logging sensors were also transmitted wirelessly via a Wi-Fi network to a cloud-based system. Email alerts were sent to the Quality Manager and GMDP operations officer if the set parameters had been exceeded with alert limits 17 – 23 C.

There were two cleanrooms accessed through the same change room, which all had been designed to meet Grade D requirements. The finish of these was appropriate. A service contract was in place for annual verification. Clean room ■ had a laminar air flow cabinet in.

Fridge items were minimal and stored in the fridge with separate area for released and quarantined stock. There was a data logging sensor probe inside the fridge which was read daily and connected to the software. Alarms triggered if temperature was outside 3-7 C. Fridge items were distributed in approved shipping boxes and only one delivery could be organized at the time. However, there was no record of 'gel packs' conditioning activity.

C7 Documentation

API registration was reviewed and it reflected activities done by the site. The site stated that the annual report 2021 was filed with MHRA but hasn't been verified yet.

All changes to Procedures were done through the Change Control system (Procedure ■). Documents were stored electronically on a shared drive with password-controlled access being limited to "read only" unless the forms are macro controlled for electronic completion, in which case a template and working copy were stored. Procedures were version controlled; superseded versions electronically archived. Procedures and Worksheets were reviewed every three years minimum. The Quality Manual and Site Master File reviewed every two years.

C8 Production

Receipt of Materials was recorded on the ■ system, batch number allocated with batch traceability. Upon receipt and before acceptance, containers were examined visually for correct labelling, damage, broken seals or any evidence of tampering or contamination. Purchased APIs and Excipients undergone through the approval process at APS and information was recorded on a Raw Material worksheet created for each received product.

Repackaging and Relabelling

The repackaging was carried out in one of the two clean rooms in the warehouse. Only one material was allowed to be re-packaged at a time and disposable equipment was utilised. The room was cleaned in between operations. High Risk products such as cytotoxic, radioactive, light sensitive or explosive materials were not repacked at APS. Steroids were purchased and distributed, the only repacking activity involving a steroid was ■ with additional measures in place to avoid contamination risk. As mentioned in section C4, there was no formal contamination risk assessment although there were various measures in place, such as handling one powder material at the time, disposable Tyvek suits, masks, spillages, cleaning agents etc.

Repacking activities were recorded on a Repacking worksheet which was specific to each individual product and pack size and contained information about repackaging container type. . Yield checks were performed by the person responsible for release of the product. 10% of containers was weighed on checks, if the contents are not visible by sight and the weights were recorded on the repacking form. Labels required 'expiry/ retest date' but it was not specified

which of those dates was printed in line with the certificate of analysis. Also, labelling procedure didn't provide any instruction about creating labels and labelling of the 'nonstandard weight' container, so a deficiency was raised.

Several records were reviewed:

- [REDACTED]
- [REDACTED]
- [REDACTED] which was only re-labelled and it was noticed that the label on the material had incomplete batch number e.g. [REDACTED] was missing.

Process Validation and Hold Time Studies were not applicable as the site was an API importer/exporter/distributor.

C9 Quality Control

No testing of materials was undertaken by the site or by an outsourced laboratory.

The product quality was determined and verified by the certification of the manufacturing facilities and the standards the API was manufactured and tested to. APS defined the quality of an API to a customer prior to an order being accepted and ensure customer approval prior to the goods being despatched. The Customer was informed of any change in quality or manufacturer.

When all the documentation was checked and finalised in accordance with the raw material worksheet, the product was released into stock by a designated releasing person. After release the items was moved physically into stock and the quantity and shelf location number were entered into stock on the computerised system.

Stability

There was no stability testing conducted by the site. The active substances were packed in the same type and material of the container as those originally used by the supplier/ manufacturer and the same expiry/ retest date assigned. In most of the cases it was HDPE container. Any change of packaging material required supplier's input. For any other situation Pharmacopeia was consulted and were available ASMF parts.

Environmental monitoring was performed once a month in the cleanrooms (see Procedure [REDACTED] - Monitoring). Contact and Settle Tryptic Soy Agar and Sabouraud Dextrose Agar plates were processed by [REDACTED] at [REDACTED] and the results issued to the Quality Department.

The investigation of OOS result was reviewed, [REDACTED] 6-Jul-20 - Micro results for the front of the changing room have come back out of specification, Contact plate [REDACTED] (Changing room near wall) returned a result of [REDACTED] against a limit of [REDACTED]. This was the first time any of the contact plates had returned OOS and none of the other plates were out of specification including the changing room clean side. A deep clean was undertaken and the plates replaced and tested. No OOS was then detected. Retraining on cleaning and changing process was conducted.

C10 Outsourced Activities

The clean room microbiological monitoring QC is outsourced to [REDACTED]

C11 Complaints and Product Recall

The procedure that covered process was Complaints, [REDACTED] 24/01/2020. A complaint was raised when there was a quality defect in either a service or goods handled by Active Pharma

Supplies. This can either be a complaint by APS to the supplier or a complaint from the customer to APS and it had to be identified either "from a Customer" or "to a Supplier" and Form [REDACTED] had to be completed. Investigation was required and may in turn lead to a complaint being taken up with APS suppliers. All complaints were defined as Low, Medium or High depending on the severity of their impact. Low Risk and Non GMP complaints may need no further action. The procedure hadn't been followed and there were no complaints trends prepared. Procedure didn't require records to keep response and date when it was sent to complainant.

The following examples were examined:

- [REDACTED] – the product should have been sent on a pallet, but was in van and probably damaged
- [REDACTED] – supplier complaints the product was sent out of cold chain and conditions required according to the CoA; rejected
- [REDACTED] – CoA mix of batch numbers

According to the procedure [REDACTED] 24/01/2020, On receipt of the information the responsible personnel had to ensure the recall was dealt with efficiently and effectively. A recall was driven by a customer complaint or from a request from a supplier or manufacturer to remove or return a product due to a safety or efficacy problem or via QMS review or pharmacovigilance risk assessment. MHRA notification was required, but MHRA mail address had not been updated. A dummy recall was planned annually with aim to identify any issues with the process and improve it upon.

The site stated that they were generally not accepting API returns.

C12 Self Inspection

The self-inspection procedure was [REDACTED] Audits were planned per topics and on annual basis covered all topics. The 2021 schedule was in place and was similar to 2020. Records were reviewed and it was noticed that [REDACTED] from 30/08/2020, were not signed and there was no tracking of completeness of it. A deficiency was raised.

C13 Distribution and shipment (including WDA activities if relevant)

The list of approved courier and subcontractors was available. New QTA with a temperature-controlled courier network for when it is required was in place.

The customer assessment was done in line with the procedure [REDACTED] 29/04/2021. The Quality Manager provided new customers with an application form prior to a sale being authorised. The details on the returned form were checked and verified by the Quality department to ensure the customer was authorised to accept APIs and the company had passed a financial risk assessment if credit is required. The source for checking of UK licences was not adequate. For customers who wish to receive [REDACTED] from APS an additional form [REDACTED] had to be completed.

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

None.

C15 Annexes attached

Annex 1 site risk rating

Section D **List of Deficiencies**

D1 Critical

None

D2 Major

- 2.1 The Quality Management System was found deficient:
- 2.1.1 The Management Review process was deficient in the following:
- 2.1.1.1 The procedure [REDACTED] 24/01/2020, didn't determine quorum for the QMS review meetings.
- 2.1.1.2 There was no set agenda which would cover topics as expected according to the relevant procedures; for example, trends for complaints, change controls etc.
- 2.1.1.3 There was no Minutes of Meeting held in June 2020, although the site stated that the meeting was held remotely.
- 2.1.2 The change control system was deficient in that, but not limited to:
- 2.1.2.1 The procedure [REDACTED] 24/01/2020 was silent about any amendments after the change control implementation started.
- 2.1.2.2 There was no evaluation of the first batches produced or tested under the change, after the change has been implemented.
- 2.1.2.3 The procedure required for change controls to be part of the standard 6 monthly quality review as well as looked at opportunistically based on results of any CAPAs, but this could not be demonstrated by the site.
- 2.1.3 There was no formal risk assessment of contamination and cross-contamination controls which assessed all risks, all areas, processes and measures in place.
- 2.1.4 The self-inspection record, [REDACTED] [REDACTED] from 30/08/2020, had not been signed nor tracked for action completeness.
- EU GMP Part II 2.11, 2.12, 2.15, 2.18, 2.20, 2.21, 2.51, 13.15, 17.40
- 2.2 The labelling process was deficient in the following:
- 2.2.1 There was incomplete batch number printed on the label of [REDACTED] instead of [REDACTED] as the data from manufacturer (label and CoA) indicated.
- 2.2.2 Labelling procedure didn't provide any instruction about creating labels and labelling of the 'nonstandard weight' container.
- 2.2.3 Labels required 'expiry/ retest date' but it was not specified which of those dates was printed in line with the certificate of analysis
- EU GMP Part II 2.12, 9.35, 9.40, 9.42, 9.43, 9.45

D3 Others

- 3.1 Complaint and Product Recall processes were deficient in that:
- 3.1.1 There was no complaints trending performed as required per procedure [REDACTED] 24/01/2020. In addition, the complaint log didn't enable easy distinguishing between a complaint made by APS to the supplier and a complaint from the customer to APS.
- 3.1.2 The Complaints procedure didn't require to keep records of response

- 3.1.3 and date when it was sent to complainant.
MHRA Contact details in the procedure [REDACTED]
24/01/2020, were not up-to date.
- EU GMP Part II 15.11, 15.12, 17.70, API GDP 7.6(vii)
- 3.2 Documentation was deficient, for example:
- 3.2.1 In the procedure [REDACTED] 29/04/2021, there
was inadequate source for checking issued UK licences.
- 3.2.2 There was no record of 'gel packs' conditioning (Note: only one cold
chain delivery could be organized at the time).
- EU GMP Part II 2.15, 10.21, API GDP 4.2, API GDP 4.5

D4 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

Deficiencies were verbally accepted by those present at the closing meeting (see B3).

F2 Assessment of response(s) to inspection report

An initial response was received on 5th July 2021. A satisfactory response was received on 23rd August 2021. GMP/ GDP certification can continue to be supported.

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:

██████████

Date:

11/10/2021

Accompanying Inspector:

N/A

Date:

N/A

Annex 1

GMP Site Risk Rating

(a). Inspection Findings

Critical deficiencies this inspection:	0	Last inspection:	0
Major deficiencies this inspection:	2	Last inspection:	0
Other deficiencies this inspection:	2	Last Inspection:	8

(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		
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)

	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

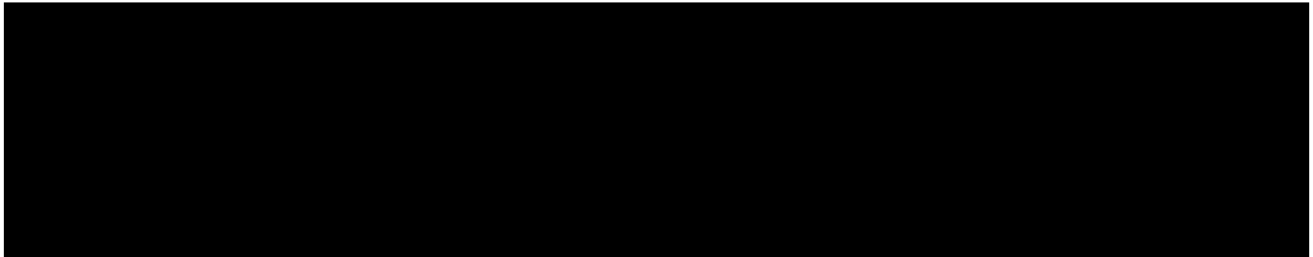
[Redacted]

(h). Conclusions

[Redacted]

**(i). Expert/ Operations Manager / Compliance Management Team (CMT) Comments
(Risk rating level 0, I, II):**

[Redacted]



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

Risk Rating:	Next Inspection target date:

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