



## **INSPECTION REPORT**

**AstraZeneca**  
Silk Road Business Park  
Charter Court  
Macclesfield  
Cheshire  
SK10 2NA

**Head Office:**  
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**Section A Inspection Report Summary**

**Inspection requested by:** MHRA

**Scope of Inspection:** Routine fee-based re-inspection, part of rolling inspection cycle for supersite.

**Licence or Reference Number:** MIA, MIA(IMP), MS, WDA(H) 17901

**Licence Holder/Applicant:** AstraZeneca

**Details of Product(s)/ Clinical trials/Studies:** The site manufactures and packages a range of dosage forms including: non-sterile solid dose, and sterile injectables.

**This inspection focussed on packaging areas for solid dose products, analytical QC laboratories, stability and procedures for manufacture of 'Specials'**

<b>Activities carried out by company:</b>	<b>Y/N</b>
Manufacture of Active Ingredients	Y
Manufacture of Finished Medicinal Products – Non sterile	Y
Manufacture of Finished Medicinal Products – Sterile	Y
Manufacture of Finished Medicinal Products – Biologicals	N
Manufacture of Intermediate or Bulk	Y
Packaging – Primary	Y
Packaging – Secondary	Y
Importing	Y
Laboratory Testing	Y
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	Y
Broker	N
Other: Specials and IMPs	Y

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

**Site Contact:** [Redacted]

**Date(s) of Inspection:** 01-02 Nov 2017

**Lead Inspector:** [Redacted]

**Accompanying Inspector(s):** [Redacted]

**Case Folder References:** Insp GMP/GDP/IMP 17901/10117-0036

**Section B General Introduction**

**B1 Background information**

The AstraZeneca, Macclesfield site covers approximately 100 acres. This is a large and complex operation and is inspected on a rotational program. The site and the associated inspection programme can be split into subparts.

1. Tablet manufacturing and the warehouse
2. Packaging operation.
3. Sterile product manufacturing areas.
4. General site systems not covered in detail during the three main manufacturing activities.

This visit covered the packaging activities and QC analytical laboratories. Applicable aspects of the quality system were inspected and the packaging facilities and analytical laboratories were inspected in full.

**Previous Inspection Date(s):** 13-15 Dec 2016

**Previous Inspectors:** [REDACTED]

**B2 Inspected Areas**

Introductions, site overview, changes, future plans, completion of actions from last inspection. Quality System associated with packaging activities; complaints, recall, deviations, CAPA, rework/reprocessing, change control, OOS, batch records, release procedures, validation, self-inspection, pest control.

Facility inspection: packaging areas, QC analytical laboratory.

**Limitations / exclusions to inspected areas**

Part of rolling inspection cycle. Refer to background information above and Annex 1 and 2

Stability testing incubators were not inspected on this occasion. The [REDACTED] packaging areas were not visited during this inspection. The contract with [REDACTED] to supply was due to expire in [REDACTED]. It was indicated that this may be extended. It may be appropriate to include this area in the scope of the next part of the rolling inspection cycle in 2018.

**B3 Key Personnel met/contacted during the inspection**

Refer to Annex 3.

**B4 Documents submitted prior to the inspection**

Document	Version /Date of document	Reflected activities on site?
Site Master File	Version 12, March 2017	Yes
Compliance Report	Dated 20 Oct 2017	Yes
Comments: Not applicable		

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## 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:**

Refer to compliance report – update of ongoing changes provided during the inspection.

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

Refer to compliance report – update of ongoing changes provided during the inspection.

The [REDACTED] packaging facility remained operational at the time of inspection

### C2 Action taken since the last inspection

Actions arising from the last inspection have generally been addressed.

### C3 Starting Materials

#### General

Incoming raw materials were not reviewed in detail during this inspection.

Sampling and testing of incoming packaging components was reviewed. [REDACTED] and [REDACTED] were received with co-shipped samples from the supplier and [REDACTED] testing was conducted for each material. The company had developed an [REDACTED] and the system provided a pass/fail result and associated printout at the time of testing. QC staff were responsible for performing the release transaction within the [REDACTED] system.

The majority of packaging component suppliers were in an approved status and samples were taken at the supplier. An audit report for a lidding foil supplier ([REDACTED]) was reviewed [REDACTED] and there was reference to review of the supplier's sampling procedures. It was however discussed that this was not specifically required within the associated global supplier qualification SOP.

Where samples were required to be taken on receipt of packaging components, these were taken in the transfer area immediately outside of the raw material sampling booth, with no formal checks on area clearance before and after use. In addition, the sampling plans were noted to be Reduced Plan [REDACTED] with no available documented justification in support of the change from General Level II – refer to section D.

#### Compliance with TSE Guidelines

Not reviewed in detail during this inspection.

#### API Compliance

Not reviewed in detail during this inspection.

### C4 Pharmaceutical Quality System

#### Deviations & CAPA

Deviation investigations were documented on paper forms and then scanned into the [REDACTED] system for electronic approval and described in procedure "Quality Incident Business Process" [REDACTED] version 20. Deviations could also be termed as 'quality notifications' in [REDACTED] as part of batch review/release activities. Investigations were routinely targeted for



closure in 7 days, but could be extended to 30 days and prior to February 2016, "Critical" deviations were named as "Major".

Critical and major deviations were assessed for repetitive trends. At the time of inspection, preventive actions were only required for critical deviations and required a CAPA effectiveness check. The time scale and frequency of the effectiveness check was determined by a risk score with the site intending to adapt the scoring system as experience was gained; extending this process to major deviations was planned for [REDACTED]. The site had a variety of forums to discuss quality events including the monthly [REDACTED] management review meeting where deviations were trended.

Several deviations were reviewed and no specific deficiencies were raised:

- [REDACTED] and [REDACTED] associated with variable data errors identified during review when embossing on line [REDACTED] with an error between using 'EXP'/'LOT' and a space that had not been included between text respectively.
- [REDACTED] Incorrect recipe selected on line [REDACTED] Root cause classed as operator unfamiliar with line, however the two test recipes on the system that contributed to the error were also removed as part of the investigation.
- [REDACTED] and [REDACTED] associated with rogue tablets/pack found in a Hoover bag and on line [REDACTED] respectively.
- [REDACTED] Failure of packing validation on [REDACTED] using [REDACTED] opaque [REDACTED] with the product transfer from [REDACTED] not progressed on the line. It was explained that in parallel to the investigation, the site was reviewing validation processes to use a risk-based approach to determine if experimental batches were required prior to validation based on knowledge/complexity of product packing.
- [REDACTED] Vacuum leak test fail on strips packed on line [REDACTED] resulting in a combination of CAPAs including an increased sealing temperature.
- [REDACTED] This was a holistic deviation report to review the trend of deviations associated with the introduction of [REDACTED] into packing, closed 27 Nov 16.
- [REDACTED] Classed as critical when deviation [REDACTED] had not been listed against all batches affected. The cause was identified, confirmed as an isolated incident and resolved.
- [REDACTED] Missing data on batch classification that meant that stock could not be released to market and was resolved with a change to the system.
- [REDACTED] Message failures between [REDACTED] and [REDACTED] systems related to an issue with the Storage Area Network [REDACTED] drive that was resolved.

#### Change control

Changes were managed within a TrackWise system. This was a global system which enabled changes affecting multiple sites within the company's network to be managed effectively. At the time of inspection, associated actions were managed either via TrackWise 'child' reports or via an Excel spreadsheet. It was discussed that the control of these spreadsheets was limited with respect to version history and updates to actions, however there was an ongoing project to update the change control system globally (expected 'go-live' date end of November 2017) which would eliminate the use of spreadsheets for change controls. The global change control [REDACTED] and associated local change control [REDACTED] for implementation at the Macclesfield site were reviewed and generally comprehensive. It was indicated that access to the system was dependent on attending the training.

Several additional change control forms were reviewed and no specific deficiencies were raised:

- [REDACTED] Move of electronic training system to a cloud-based system (same provider).

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- [REDACTED] Precautionary initiation of importation from alternative manufacturing site due to hurricane in Puerto Rico.
- [REDACTED] 'Experimental' change control for [REDACTED] mat file transfer investigation.
- [REDACTED] Introduction of night shift onto lines A1 and A2 (cancelled).
- [REDACTED] Introduction of night shift onto high volume [REDACTED] area. No formal assessment was included of whether existing cleaning practices were adequate for the additional activity in the area however other details were generally comprehensive.
- [REDACTED] Introduction of offline aggregation line.

#### Specials

No changes had been made to the relevant procedures since the previous time this was inspected. Four operations between 2016 and the time of inspection had been conducted under the provisions of MS17901 and all were for the product [REDACTED] or named patient supply in South Africa. On review of the licence, it was discussed that [REDACTED] should be removed from the activities authorised as these were not used.

#### **C5 Personnel**

Staff met during the inspection were knowledgeable of their areas of responsibility and were able to discuss their processes and procedures confidently.

Training records were not specifically reviewed during this inspection.

#### **C6 Premises and Equipment**

##### Packaging areas

Packaging areas were located within the pharmaceutical production building (PPB). Several areas were used and these were linked by a series of corridors and stairwells. An update on the ongoing project to relocate the packaging areas was provided. This was in conjunction with the construction of a new automated highbay warehouse, with the existing warehouse areas being converted to house the packaging lines. A presentation relating to this project has been saved to the case folder.

It was noted that the humidity limits applied in the room used for packaging [REDACTED] were 1 [REDACTED]. Although the product was not exposed for extended periods in this area, the company was requested to investigate and review supporting product data to confirm if these applied limits were appropriate. The humidity in the room at the time of inspection was approximately [REDACTED].

##### Validation

A selection of the validation summary documentation supporting the implementation of the [REDACTED] [REDACTED] was reviewed and was generally acceptable, however it was noted in the product impact assessment that the same classification rationale wording for severity had been used for three different levels of severity. The inspector did not raise any concerns with the severity classifications in question, however it was not clear why the same rationale description had been used. Documents reviewed:

- Validation Plan [REDACTED]
- URS [REDACTED]
- Process Information [REDACTED]
- Process Impact Assessment [REDACTED]
- Qualification Plan [REDACTED]
- IQ Report [REDACTED]



- IQ Report [REDACTED]
- IQ Report [REDACTED]
- OQ Report [REDACTED]
- Validation Report [REDACTED]

## C7 Documentation

### Electronic Batch Records

The electronic batch record (EBR) system also referred to as a [REDACTED] manufacturing execution system (MES) was reviewed. The system interfaced with [REDACTED] and the warehouse management system (EWM). It did not interface with the equipment control systems, all changes to the MES configuration went through the site change control process and SOP [REDACTED] version 4 described access control for the system. Business continuity for the system varied depending on the process and time criticality of the activity. The rules for creating the approved manufacturing batch record templates were described in the "F [REDACTED] master batch record creation, testing and publishing" procedure SOP [REDACTED] version 2 with instructions for equipment cleaning included as part of the batch records which meant that the equipment status function of MES was not being used at the time of inspection.

An EBR for packaging of [REDACTED] from 19 Jun 17 on [REDACTED] was reviewed. Comments entered during manufacture of the batch were captured as [REDACTED] these included system generated exceptions and required approval as part of batch record review. It was discussed that where exceptions required greater technical understanding of the system, QA had support from subject matter experts to facilitate the review to determine batch impact. No comments were raised.

### Quality Events

The [REDACTED] system issued unique numbers for quality events with the prefix indicating the type of event, i.e. prefixes of 1, 3 or 9 indicated a deviation, CAPA or batch comment respectively. A typical number would be [REDACTED], which was abbreviated by the site as reference [REDACTED]

## C8 Production

Packaging materials were delivered from the warehouse area to a 'NOF' (next order footprint) area adjacent to the respective packaging line. These were checked onto the lines via the electronic batch records (EBR) system using barcode scanners. Operations on line [REDACTED] [REDACTED] product were observed during the inspection. The EBR using the [REDACTED] interface confirmed the material approval status had not been blocked at the point of receipt at the line and guided the operators through the packing process, automatically triggering in-process checks (IPCs) based on volumes. At the time of inspection, the EBR was configured that on completion of a pallet, IPCs were triggered, which dependent on the line speed was described as typically every 15 minutes for operation of line A1. Each operator had a unique user ID and password. Instructions were through operator prompts in the EBR with the detail of how to perform the operation being described in the related procedures. SOP [REDACTED] 6 version 15 that described how to perform in-process tests on lines A1 and A2 for the checkweigher setup tests was reviewed and no comments were raised.

Each of the packing areas were inspected except for the [REDACTED] area. Controls appeared to be generally similar for each line and it was discussed that when the new packaging facility is commissioned that the material flow will improve.

The packing lines observed, grouped by area and including product where noted were:

- Lines [REDACTED]
- Lines [REDACTED]

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- Lines [REDACTED]
- Line [REDACTED]
- Line [REDACTED]
- Lines [REDACTED]
- Line [REDACTED], [REDACTED] (with time out of cold storage calculations discussed for [REDACTED] and associated deviation [REDACTED]).

Lines [REDACTED] and [REDACTED] were described as de-commissioned at the time of inspection and these rooms were not inspected.

The line clearance process was performed against the relevant line SOP, with one e-signature entered into the EBR, with a second signature entered following the line clearance checks. There was no procedural control however to require a deviation to be raised if the second check highlighted a cleaning failure – refer to section D.

The company used a live line clearance process on a routine basis for all staff performing this task. A variable number of items were placed on the line and all must be noted for a successful requalification. It was discussed that at least one item was placed on the line for the clearance checks and a 'zero challenge' was not undertaken.

Product contact parts were washed in a shared room within the PPB. Procedural controls were in place to restrict the cleaning of parts from one line / product at a time, however some issues were noted with the supporting documentation. In addition, some parts remained in the area despite the associated documentation indicating that the area was clear and ready for the next use at the time of inspection – refer to section D.

## C9 Quality Control

### QC facility inspection

Both QC chemical and physical laboratories in quality assurance building 1 and 2 were inspected, including both sample receipt areas, the 2 large laboratories in building 2 for bulk drug and formulated product testing and the 4 large laboratories in building 1 for formulated products testing. There were 3 small rooms in building 2 for ICP, particle counting and for light-sensitive products. There were two Zoladex testing laboratories to provide contingency in case of disruption to one. The laboratory in building 2 was performing most of the testing with approximately 40 standalone incubators at the time of inspection and that were connected to the site EBI system for monitoring and alarms.

A monthly preventive maintenance schedule of HPLCs was performed in-house with Waters performing an annual 'OQ' service visit. Tablet processing workstations (TPW) were used to automate sample preparation with cleaning of the homogeniser discussed with form 901883 version [REDACTED]

[REDACTED] was used for data acquisition from all HPLCs and GCs; each analyst was issued with their own system suitability and standard preparation log. Sample preparation for uniformity of content [REDACTED] was observed with the usage log for a UV spectrophotometer reviewed.

Controls to ensure that all QC test results were reported and reviewed was discussed with the [REDACTED] operation procedure SOP [REDACTED] version 10 that required that the local administrator performed a quarterly review that all sign offs had been completed correctly.

Solid reagents were observed with a five-year expiry once opened. For the examples viewed these were based on the recommendation from the manufacturer with the site also referencing that WHO guidance was being followed. It was discussed whether a risk-based approach may be applicable for applying expiry dates and this may be of interest at a future inspection.



From the areas observed, equipment was calibrated with reagents and standards stored appropriately and glassware was in good condition. No deficiencies were raised.

#### OOS procedure

The OOS procedure was SOP [REDACTED] version [REDACTED] was reviewed for batch [REDACTED] which was rejected due to high Rosuvastatin content and was related to a mechanical load cell issue at the manufacturing site in [REDACTED]. The manufacturing site did not perform QC testing with this essentially contracted out to the Macclesfield site for ROW testing in addition to performing EU import testing. Samples from the original analysis had not been retained to aid the OOS investigation as required by the procedure and a deficiency was raised.

The following OOS investigations were reviewed and no specific deficiencies were raised:

- [REDACTED] batch rejected due to high Rosuvastatin content.
- [REDACTED] batch rejected due to high Rosuvastatin content.
- [REDACTED] (3 months), dissolution rate below specification at day 84 and related to an issue with buffer preparation used to perform the test.
- [REDACTED] mean dissolution rate for an experimental (not commercial) batch manufactured in [REDACTED]

#### Stability

Stability was not inspected on this occasion.

### **C10 Outsourced Activities**

Whilst the majority of testing required is conducted on site, the company names several contract QC laboratories on their licences. The written agreement with [REDACTED] was reviewed and found to be generally acceptable.

The site pest control programme was subcontracted to [REDACTED], which provides a number of services across the campus. [REDACTED] further contracted this activity to [REDACTED]. The contracts between [REDACTED] and the respective service level agreement between [REDACTED] and [REDACTED] were reviewed and no specific issues were noted.

### **C11 Complaints and Product Recall**

#### Complaints

Several complaint investigation reports were selected for review. These were generally acceptable however one deficiency was raised. Examples reviewed:

- [REDACTED] - missing label on vial of [REDACTED] Isolated incident.
- [REDACTED] - different colour intensity in the carton. No sample was provided however photographs were. It was noted that although the colour difference was within the acceptable [REDACTED] a question was asked of the complainant whether they were aware of any suspicions on authenticity and no follow up had been documented regarding a response.
- [REDACTED] - incorrect blister in pack. Whilst the investigation was acceptable, the initial classification of the event was 'no investigation required' based on an initial review. This was not in line with the requirements of the complaint SOP which would require a full root cause investigation to be initiated for a complaint of this nature – refer to section D.
- [REDACTED] - incorrect blister in pack. This was similar in nature to [REDACTED]

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Recall

A recall had been conducted since the previous inspection [REDACTED] where product was released and shipped to [REDACTED] with the wrong packaging. The investigation report was reviewed and appropriate actions had been taken.

**C12 Self Inspection**

The programmes for self-inspection (locally within departments, reviewing compliance with procedures) and internal audits (across functions, reviewing compliance of procedures with regulatory expectations) were described in SOP [REDACTED]. The internal audit schedules for 2016 and 2017 to the time of inspection were reviewed and found to be generally in control.

**C13 Distribution and shipment (including WDA activities if relevant)**

Not reviewed during this inspection.

A separate GDP inspection was conducted in August 2017 (Ref: Insp GDP 17901/10117-0034). The deficiencies noted during that inspection had been addressed.

**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**

**1 CRITICAL**

None

**2 MAJOR**

None

**3 OTHERS**

**3.1 Sampling activities for printed packaging components were deficient in that:**

3.1.1 There was no documented information available for review to support the change from General Inspection Level II to Reduced Plan [REDACTED] for the inspection of incoming [REDACTED] labels. In addition, it was not clear which [REDACTED] was being used.

3.1.2 Sampling of printed packaging components was not performed in a designated area with associated documented area clearance checks.

**Reference: EU GMP Part 1, Chapter 3 (3.22); Annex 8 (5)**

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**3.2 Production controls were deficient in that:**

- 3.2.1 Form [REDACTED] in the parts wash bay had been signed to confirm that all change parts were clean, dry and removed on [REDACTED] however product/dust extraction hoses were observed on [REDACTED] that had not been removed.
- 3.2.2 The line clearance and changeover procedure [REDACTED] did not describe the practice that an Exception would be raised in the [REDACTED] if a second check identified that a line clearance was unsatisfactory.
- 3.2.3 Challenges for electronic code readers were not adequately carried out to ensure that the optical character recognition camera system was operating correctly as the challenge only included gross defacement of the variable data.
- 3.2.4 Controls to minimise the risk of mix-up were weak in that the overflow carton conveyor chute hatch on line A1 had not been locked as required.

*Reference: EU GMP Part 1, Chapter 4 (4.1, 4.21g); Chapter 5 (5.49, 5.57)*

**3.3 Examples were observed where procedures had not been complied with:**

- 3.3.1 Samples had not been retained as required by SOP [REDACTED] to support the phase 1 investigation of [REDACTED]
- 3.3.2 Complaint references [REDACTED] and [REDACTED] relating to wrong blisters in cartons had been classified as 'no investigation required' based on initial review of information. This was not in line with the procedure which would require full root cause investigation for a complaint of this nature.

*Reference: EU GMP Part 1, Chapter 1 (1.8v); Chapter 4 (4.1)*

**4 COMMENTS**

- 4.1 The company was requested to investigate and review available information relating to the [REDACTED] product and whether the humidity limits of [REDACTED] applied in the packaging room were appropriate.

**Section E Site Oversight Mechanism**

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

**Section F Summary and Evaluation**

**F1 Closing Meeting**

The closing meeting was held with individuals listed in B3 and the deficiencies were verbally accepted in a positive manner. The company committed to addressing the issues.

**F2 Assessment of response(s) to inspection report**

A response was received on 30 Nov 2017 which was generally satisfactory. Additional clarification for two points was requested from the company on 01 Dec 2017 and further responses were received on 13 Dec 2017 which were deemed to be satisfactory.

**F3 Documents or Samples taken**

Electronic copies of the company's presentations during the inspection were provided and saved to the inspection case folder.



**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
Directive 2001/83/EC, Directive(s) 2003/94/EC and 2011/62/EU	✓
GMP as required by HMR 2012 (as amended)	✓
Directive 2001/20/EC	✓
Directive 2001/82/EC	N/A
Article 84 and Article 85b(3) of Directive 2001/83/EC (GDP) and 2011/62/EU	✓

and is acceptable for the products in question.

**Name and Dated Signature of Inspector (s):**

**Signed:**  
Name:

[Redacted Signature]

**Dated:** 19 Dec 2017

**Accompanying**

**Inspector:**

[Redacted Name]

**Dated:** 19 Dec 2017

Name:

[Redacted Name]

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**Annex 1**

**GMP Site Risk Rating**

**(a). Inspection Findings**

Critical deficiencies this inspection:	0	Last inspection:	0
Major deficiencies this inspection:	0	Last inspection:	1
Other deficiencies this inspection:	3	Last Inspection:	1 (+3 for IMP activities)

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

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

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**(d). Inspectors Comments Related to Discriminatory Factors**



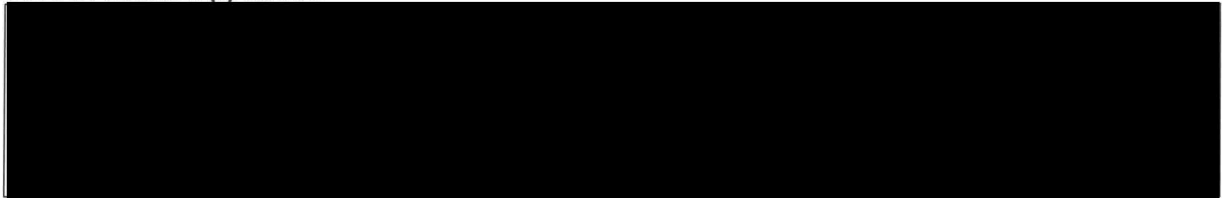
**(e). Risk Rating Result Incorporating Discriminatory factors (✓ applicable box)**

Risk rating level	Inspection Frequency	Inspector Proposed Risk Rating (✓)
0	Immediate (as soon as practicable)	
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**

Not applicable

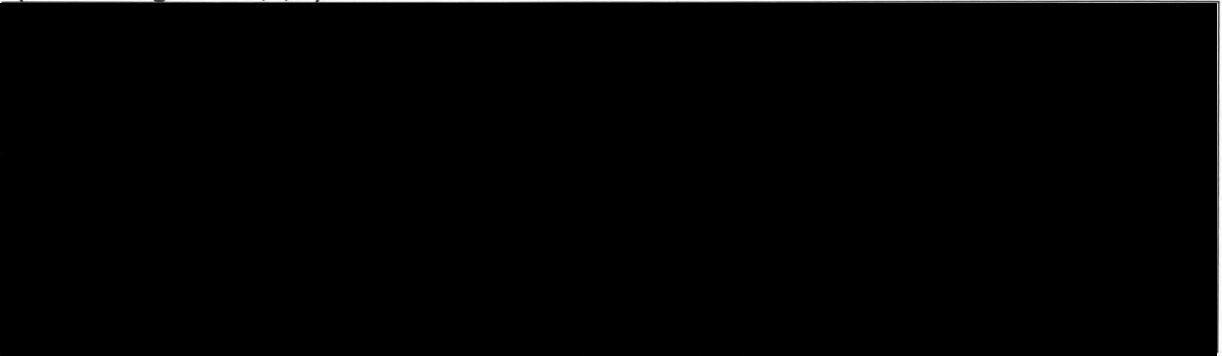
**(g). GMP or GDP certificate conditioning remarks required as a result of risk-based decisions noted in section (f) above**



**(h). Conclusions**



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



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

Risk Rating:	Next Inspection target date:

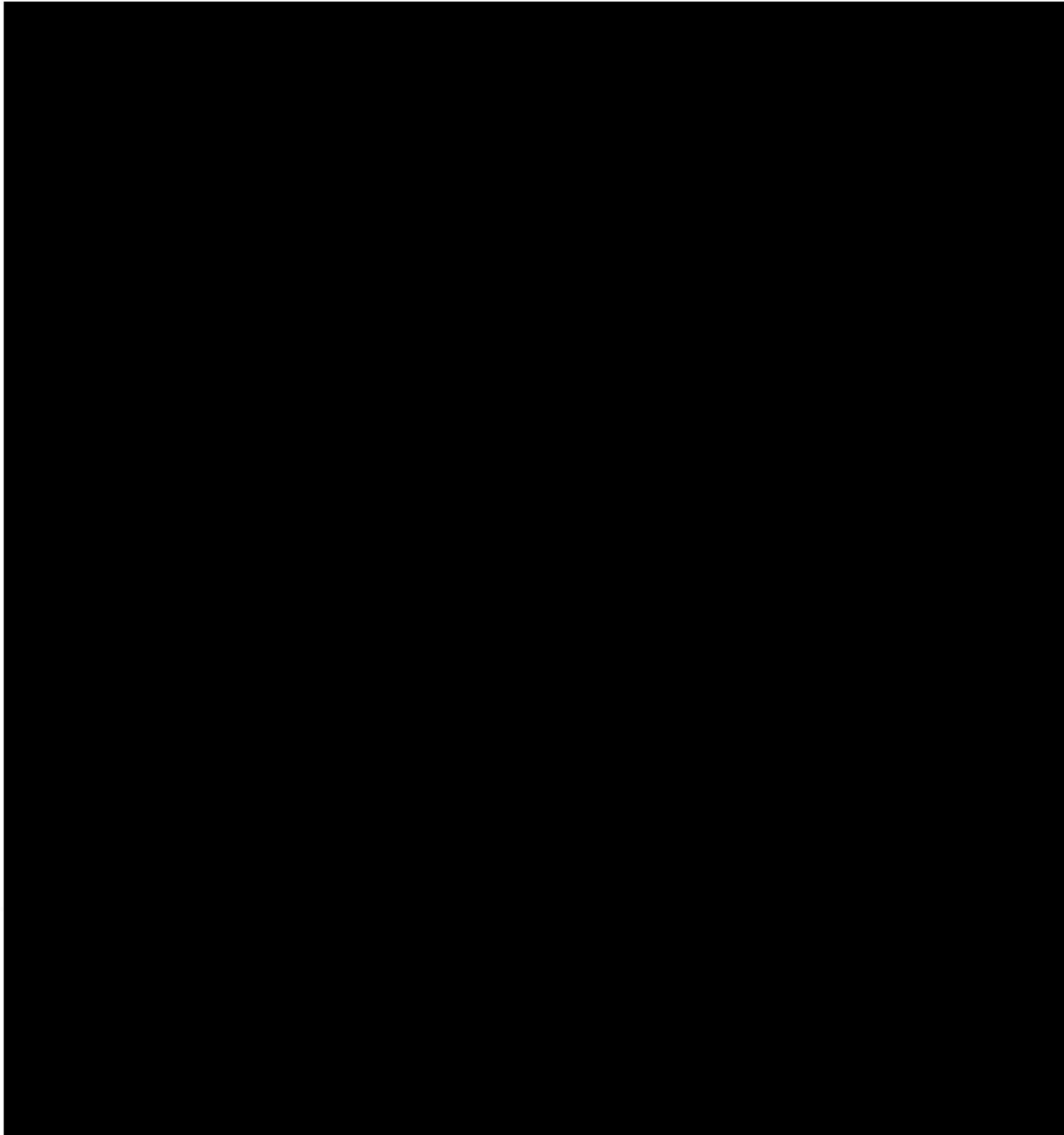
***Notes regarding re-inspection and GMP certificate validity***

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.gsi.gov.uk](mailto:gmpinspectorate@mhra.gsi.gov.uk)

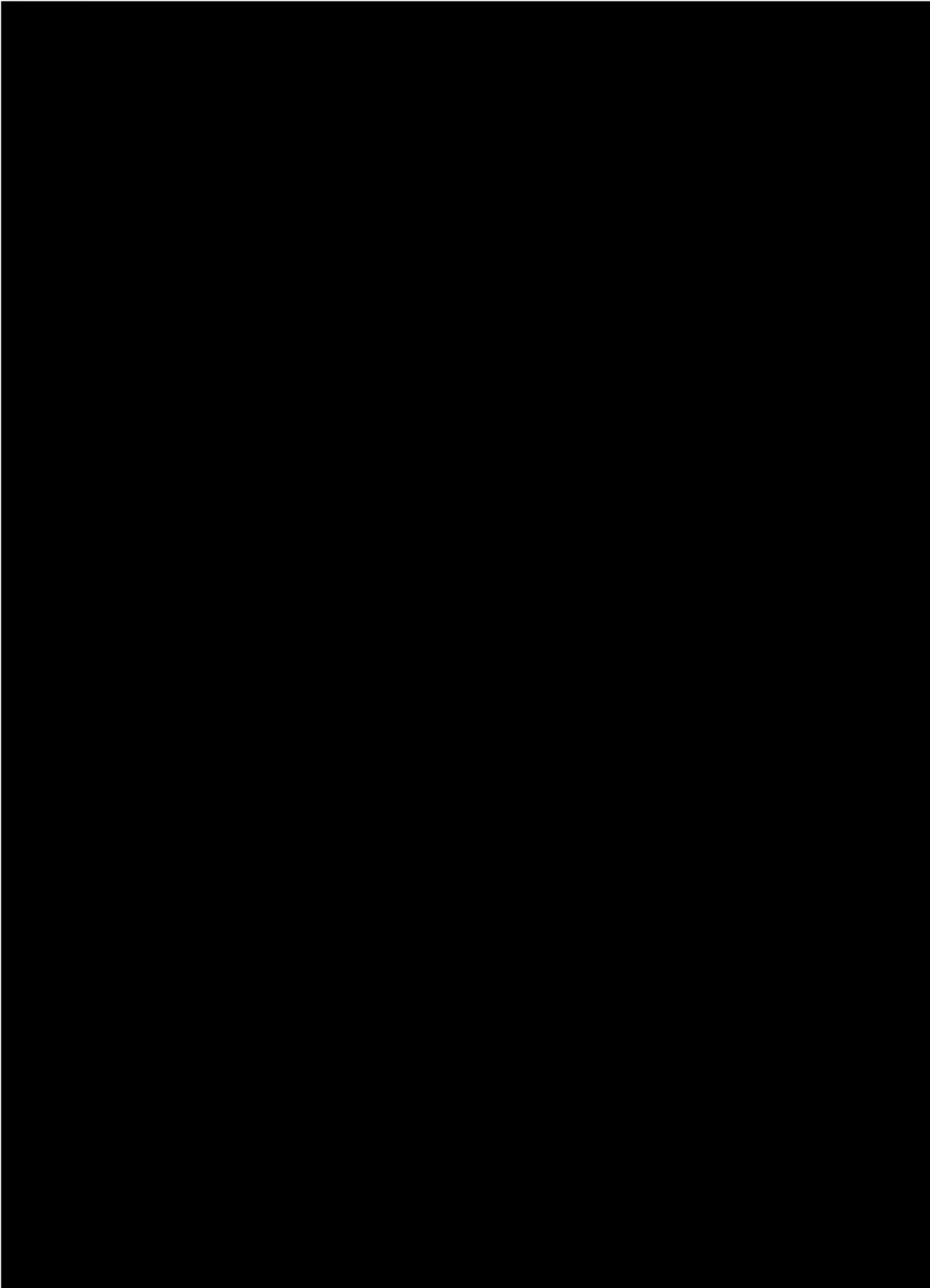
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