Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

Phil Inter Pharma Co Ltd
No. 20, Huu Nghi Boulevard, VSIP
Thuan An, Binh Duong
VN-590000
Viet Nam

and

No. 25, Street No. 8, VSIP
Thuan An, Binh Duong
VN-590000
Viet Nam

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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Re-Inspection

Licence or Reference Number: PL 20395/0485

Licence Holder/Applicant: Relonchem Ltd

Details of Products: [redacted]

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

Name and Address of sites inspected (if different to cover):
The inspection covered two sites:

The soft gelatin capsule manufacturing site was referred to as Plant 2 and was located at No. 20, Huu Nghi Boulevard, VSIP, Thuan An, Binh Duong, VN-590000, Viet Nam (MHRA site number 14673770).

There was a separate QC testing facility at Plant 1, located approximately 2 km away at No. 25, Street No. 8, VSIP, Thuan An, Binh Duong, VN-590000, Viet Nam (MHRA site number 15275896).

Site Contact: [redacted]

Dates of Inspection: 18 – 21 Nov 2025

Lead Inspector: [redacted]

Accompanying Inspector: [redacted]

Case Folder References: Insp GMP 46387/14673770-0004, Insp GMP 46387/15275896-0003

Section B General Introduction

B1 Background information

The parent company was based in South Korea, and in 2004 had constructed a manufacturing facility (known as Plant 1) in the VSIP industrial park outside of Ho Chi Minh City. A second facility (Plant 2) was constructed nearby in 2013, and this facility was the subject of the inspection. At the time of the current inspection, Plant 2 held approvals from the [redacted]

Plant [redacted] manufactured soft gelatin capsules for [redacted] In addition to the [redacted] they also supplied [redacted] The largest markets were [redacted]

Previous Inspection Date: 11 - 14 Oct 2016

Previous Inspectors: [redacted]

B2 Inspected Areas

Management review
PQRs
Change control
Deviations and CAPA
OOS/OOT/laboratory investigations
Complaints
Recalls
Returns
Training
Self inspection
Artwork controls

Starting material controls: API audits, excipient risk assessments, TSE
Export and transportation
Process validation
Cleaning validation
Analytical method validation
Equipment qualification, calibration and maintenance

Facility tours:
Warehouse
Manufacturing and packaging
QC/micro/stability labs
Utilities – HVAC and purified water

Limitations / exclusions to inspected areas

None

B3 Key Personnel met/contacted during the inspection

Name	Position
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
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[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	[redacted] Oct 2025	Y
Compliance Report	14 Oct 2025	Y
Comments: None		

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:

A number of new AHUs had been installed since the previous inspection. Various items of production equipment had also been added, including a new gelatin melting tank, encapsulation machines, blister machines and cartonning machines.

Several new products had been introduced to the site.

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

The site planned to add [redacted]

C2 Action taken since the last inspection

The commitments arising from the previous inspection had been implemented.

C3 Starting Materials

General

The Vendor Qualification procedure was [redacted] and was applicable to APIs, excipients and packaging components. The R&D department would identify any potential new or alternate suppliers, and these would then be evaluated by QA under change control. It was acknowledged that API changes would also require prior regulatory approval.

Pre-shipment samples were requested, and various documentation requests were made including a vendor questionnaire, elemental impurities, nitrosamines and TSE certificates. QC would perform analysis of the samples against the material specification.

Packaging materials underwent a similar qualification exercise, and this could include test trials on the packaging lines.

Audits were required for APIs, key excipients and primary packaging materials every 3 years. Audits could be on-site or remote, or provided by a third-party auditor if their qualification and experience was satisfactory, if there was a contract in place, and there was a declaration that there was no conflict of interest.

The only material identified as a 'key excipient' was the gelatin used in the capsule shells. Gelatin was sourced from [redacted] in [redacted] The site had been reaudited in Sept 2023 by Phil Inter Pharma Co Ltd. The site held Korean MFDS and US FDA approvals, and the gelatin had a CEP. The site also operated to ISO9001 and HACCP standards. The key starting material was bovine hide sourced from the USA (Class II TSE risk), with no high-risk components such as brain or spinal cord used in the manufacturing process.

If the audit identified any critical issues the supplier would be rejected. No more than 5 major deficiencies would support approval; more than 5 majors led to a status of 'conditionally qualified' and a shortened audit frequency.

Once approved, new materials/suppliers were added to the approved vendor list. There was also a process for ongoing review of existing suppliers, which included an assessment of previous deliveries, test results, updated regulatory approvals and a review of service levels.

There were tracking logs used to monitor vendor status, and a current audit schedule was also provided. No issues were noted.

Document [redacted] (Aug 2024) was a risk assessment for the excipients used in [redacted] for the UK and was aligned with current EU and PIC/s guidance. No issues were noted with how the guidance had been applied, other than not acknowledging the history of contamination risks at a global level for materials such as [redacted] The inspector commented that if the excipient risk assessment included this factor it could then be used to drive a risk reduction action such as carrying out [redacted] testing on every container of [redacted] (see also Section C9, quality control).

Compliance with TSE Guidelines

TSE certificates were required as part of the vendor approval process (see above) and were re-evaluated during the periodic vendor requalification. Current TSE certificates were seen for [redacted] API and gelatin.

API Compliance

The API approval process included an evaluation of supporting documents such as the DMF/CEP and GMP certificates.

The [redacted] API was manufactured by [redacted] and the site had been audited in Sept 2024 by [redacted]. The site also held GMP accreditations from US FDA and France, and the Dutasteride was supported by a CEP and a Written Confirmation. The audit report was sufficiently detailed, and the CV of the auditor was also included.

C4 Pharmaceutical Quality System

Product Quality Reviews

The procedure for PQRs was [redacted] and applied to all commercial products in all markets. The PQR schedule was intended to cover the calendar year, with the reports to be issued by the following February. The SOP was sufficiently detailed and also included information on what to include in the PQR in the event that no batches had been manufactured during the review period. Example PQRs were requested for [redacted] and for [redacted]

The last two completed PQRs for [redacted] were reviewed, covering the years 2023 and 2024. The product was packed in alu-PVC blisters and had a [redacted] shelf life when stored below 30°C. It was supplied to the [redacted] market. In 2023 there had been [redacted] batches manufactured, and in 2024 a further [redacted] batches. All raw material, packaging component and finished product tests were within specification and no adverse trends observed. Key processing parameters were consistent, and all IPC tests met the requirements. Ongoing stability data continued to support the shelf life. No deviations, OOS or complaints were recorded, and no significant changes.

The 2024 report for [redacted] was the first PQR for this product, covering [redacted] batches supplied to [redacted] The product contained two APIs ([redacted]) and had a [redacted] shelf life. Again, no issues were noted, and the report was suitably detailed.

Deviations

The deviation procedure was [redacted] and allowed for both planned and unplanned events. All deviations were to be raised as soon as possible and forwarded to QA. There was a check for repeat deviations or common root causes.

Unplanned deviations were subject to impact assessment and investigation and were classified as critical/major/minor – these categories were clearly defined in the SOP. The extent of investigation, and the timelines for completion, were defined for each category. Deviations would be copied to the UK MAH and QP, where relevant.

Planned deviations were treated as temporary changes and would typically be used for planned delays in maintenance schedules or to release materials for use prior to completion of all QC tests. No planned deviations had been used in the last two years.

There had been 3 unplanned deviations raised in 2023, 4 in 2024 and 2 to date in 2025. Three examples were requested:

[redacted] arose when the 18m stability samples of [redacted] batches of [redacted] were not pulled for testing. The issue was discovered when the 24m samples were scheduled for removal and the 18m samples were noticed to be still present in the chamber. All other samples required to be pulled at the same time had been removed, and this appeared to be an isolated error. Analysis of the 24m samples did not show any issues with the batches. Appropriate CAPA were implemented (see below).

[redacted] was raised when a batch of [redacted] was noted to be tested to EP & USP specifications, whereas the batch record required KP specification. The differences in specifications and test methods were clarified, and the batch was resampled and tested to the KP specification. It was noted that several raw materials had multiple pharmacopoeial specifications; normally they would be tested to the appropriate specification depending on the intended use in the production schedule, and a check was in place to ensure that materials of the correct specification were issued into production. Where a batch was required for use in a different product with a different specification, it would then require a deviation in order for it to be retested against the new pharmacopoeial specification. CAPA had been raised to ensure that warehouse staff and IPQA carried out the appropriate checks during material issue and receipt into manufacture.

[redacted] occurred when the camera of blister machine [redacted] was unable to detect missing or rogue capsules. Manual inspection was implemented on the primary packaging line,

with an additional manual check in the secondary packaging area; this was in place for 2 weeks until the repair was complete. The camera vendor was contacted and an investigation established that the input/output controller was damaged. A change control was raised for its replacement, and this was requalified under report [redacted]

CAPA

The CAPA procedure was [redacted] CAPA could arise from multiple sources such as deviations, self-inspections, external audits, regulatory inspections, complaints, recalls, OOS, PQRs, risk assessments, etc. There was a process for effectiveness checks, either through monitoring of other systems such as PQRs, self-inspections, management review, etc or by specific spot checks.

A total of 10 CAPA had been raised in 2023, and a further 15 in 2024. Most of these were as a result of self-inspections or external audits. Two examples were reviewed:

[redacted] was related to deviation [redacted] (see above). The primary action was a documented second person check of the prepared monthly stability schedules against the master annual schedule. A further, similar check was also implemented for the monthly calibration and PM schedules against the master schedule to prevent a similar occurrence in these systems.

[redacted] was raised following a regulatory inspection from the [redacted] authority in 2024, in relation to the absence of calibration of the cylinders used for [redacted] antibiotic potency testing in the microbiology lab. A suitable procedure was implemented and staff trained accordingly.

Change Control

Change control was managed by procedure [redacted] effective 24/03/2023, and covered changes to facilities, systems, processes, procedures and documents, such as SOPs and specifications. The SOP contained a useful process flow diagram. The process utilised handwritten forms competed with wet review / approval signatures.

Each change control required an impact assessment and categorisation dependent on the change's impact to the process (for example critical, major or minor). The SOP contained an appendix of example critical, major, and minor changes, as well as some recommended actions for different types of changes. There were no critical change controls raised at the time of the inspection. Approval to proceed with a proposed change was given by QA. Significant changes could also utilise a standalone risk assessment conducted in line with [redacted]

Changes affecting regulatory status of a product were notified to, and approval sought from, the MAH and / or QP as required. The opinion of the MAH / QP was recorded on form [redacted] - this was an improvement since the since the previous MHRA inspection.

Actions plans were documented with the body of the change control. Any extension of actions required approval from QA.

The current change control log was reviewed and contained 110 changes in progress. There were no changes specific to UK product in the list provided ahead of the inspection.

A separate log for tracking of effectiveness checks was maintained ([redacted]) and contained two open effectiveness checks.

Three change controls were reviewed:

[redacted] Introduction of [redacted] commercial batch size of [redacted] capsules for the [redacted] market. It was stated in the change control that no effectiveness check was required however no justification for lack of effectiveness check was documented. Upon further discussion it was stated that an effectiveness check was not required as there had been a 3 batch validation exercise (ref: process validation protocol [redacted] with associated stability studies as a result of the change, which proved effectiveness, however this justification

was not documented. It was recommended that the procedure be improved to require a documented justification if no effectiveness checks were to be performed. This issue was raised as part of a deficiency.

[redacted] New equipment for EU line. The change control document was written in Vietnamese and English; therefore, some portions of the document were translated by site personnel during the inspection. No issues were noted with the quality of the change control. There was good evidence of a comprehensive installation and qualification plan completed as part of change implementation, and references to supporting document were included e.g. [redacted] or PQ of encapsulation machine.

[redacted] Relocation of hot and cold spot temperature probes following temperature re-mapping of warehouse. This change was classified as a minor change however, no justification for this classification was recorded and there was no documented assessment of the potential that temperature monitoring may possibly have been taking place not in the worst-case locations. This issue was raised as part of a deficiency.

Management Review

[redacted] effective 07/11/2020 was reviewed. The meetings were conducted every three months between QA and senior production/company personnel. This included the assessment of trends for deviations, change controls, complaints, recalls and environmental monitoring, including trending for root causes, which was an improvement since the previous MHRA inspection. Slides and summary document for [redacted] from Sept 2025 were reviewed – no issues were noted.

Validation Master Plans

The site utilised an overarching VMP document reference [redacted], effective 30/12/2024, describing the site approach to validation. The document contained a series of annexes giving the current state of qualification of different systems, e.g. Annex 6A covered qualification / requalification of major production equipment, and Annex 6B covered equipment used in generation of utilities. No issues were noted.

There were additional VMPs covering process validation, clearing validation, computer system validation, analytical methods and laboratory equipment. No issues were noted.

Process Validation

The process validation VMP was [redacted] effective 09/05/2025 – no issues were noted. A process validation protocol and report for [redacted] product code [redacted] were reviewed in conjunction with the governing procedure, [redacted] effective 09/05/2025. Protocol reference [redacted] dated 07/07/2023 and report reference [redacted] dated 21/07/2023.

The validation protocol was completed by hand with data acquired during the manufacture of the validation batches. The data was then transcribed into the validation report prior to review and approval. There was no defined process for the transcription and checking of data from the protocol to the report, and the roles and responsibilities for review and approval of the validation report were not adequately defined in the governing procedure. Discrepancies in the description of roles and responsibilities were noted between the VMP, procedure and validation report. This issue was raised as part of a deficiency.

Cephalosporin risk assessment

In addition to the soft gel capsule manufacturing facility, the Plant 2 site also contained a separate manufacturing facility for [redacted] products. This building was not part of the inspection, and it was explained that there were no common staff, equipment or utilities. The two buildings even had separate scrapyards. In addition, the soft gel building had biometric access control to prevent any unauthorised access.

There was a risk assessment ([redacted] dated Nov 2016) which evaluated the potential risks of cross-contamination from the [redacted] facility. The risk assessment had been

revised shortly after the 2016 MHRA inspection to include the separate site canteen building which was used by staff from both production buildings. A program of routine monitoring had been introduced to detect trace levels of [redacted] in the canteen, and this included swab samples from door handles, tables, chairs, etc. The risk assessment was reviewed every 3 years and took into account any changes on site, and whether the swabs had identified any traces of [redacted] The latest review (June 2023) confirmed that no such incidences had occurred. During the inspection it was also noted that ground works had commenced on a separate canteen for the [redacted] plant, which was due to be completed by mid-2026.

Regulatory updates

[redacted] was for the tracking of regulatory updates. The company subscribed to various newsletters and websites from reputable pharma websites in order to keep up to date with current and pending changes. This included MHRA, EMA, Eudralex, ICH, WHO, ISO, US FDA, etc. Any identified changes relevant to the facility operations were subject to impact assessment and an action plan where necessary. In addition, there was a regular check on the validity of any relevant CEPs in case of any withdrawals. There was a separate procedure related to pharmacopoeial updates.

Records indicated that the company was aware of recent publications such as draft updates to EU GMP Chapter 1 and US guidance on transport validation.

C5 Personnel

The number of staff at Plant 2 had increased since the last inspection and was now approximately 143. The total included 36 in Production and 15 in QA. Across the two facilities in Vietnam there were 350 people employed.

Training Systems

The procedure for [redacted] effective 08/08/2025, was reviewed. The site utilised extensive leader-led training and effectiveness checks such as quizzes and written assessments however, there was no requirement to document the reading of updated versions of procedures where no leader-led training was required. It was therefore not possible to confirm all staff were trained on the latest version of each procedure. This issue was raised as part of a deficiency.

C6 Premises and Equipment

Plant 2 was a single building over 5 floors. The basement was used for packaging material storage; the ground floor was the warehouse for raw materials and finished products; the packaging areas were on the first floor; manufacturing was on the second floor; and the purified water plant and AHUs were on the roof level. Production operations were on a single day shift.

Incoming Goods and Warehouse

The warehouse for raw materials was on the ground floor of the building. A procedure for the [redacted] effective 20/12/2023 was in use.

The incoming goods inspection paperwork for [redacted] batch [redacted] was reviewed. Although there was no special storage condition required, the delivery had been accompanied by a temperature monitoring device, the data from which had been downloaded, and showed a temperature excursion outside the limits stipulated in the governing procedure ref [redacted] effective 07/06/22. The excursion limits in the procedure were between 25°C and 40°C for not more than 24 hours, and the excursions was documented as being up to 44.8°C. The temperature data had been reviewed by QA, and it was concluded that the excursion had no impact but there was no evidence or justification documented. This issue was raised as part of a deficiency.

The area was controlled between 15 to 25°C and 70% RH and was monitored by probes connected to a BMS. There were different areas for storage of quarantine, approved and rejected materials and there was sufficient space in the warehouse for the activities carried out. A cold room was in use for the storage of some materials. There were no rejected materials in storage at the time of the inspection.

The area was well maintained, in a clean and tidy condition, and pest control measures were evident.

There were two raw material sampling rooms – one for general use and another for potent materials (Separate entrances for materials and personnel into the sampling areas were in use. Additional gowning was required to enter the sampling booths via Grade D airlocks.

Posted pages from the , were available in the non-potent sampling area, however different versions of the procedure were posted – version in the material transfer room and version at the personnel entry door – this discrepancy was highlighted to staff.

Sampling of raw materials was conducted in accordance with two different procedures - effective 21/03/2025, and effective 10/10/2019. Sampling of potent products was conducted in a closed isolator for additional containment. It was stated that sampling was conducted in areas that met Grade C classification at rest. Each container of API and excipients were sampled and tested for identification. Composite samples were made for all other tests.

A mixture of reusable and disposable sampling utensils were in use (disposable utensils were used for potent products). effective 21/07/2020, described the cleaning process and prescribed a clean hold time of days. No issues were noted.

A selection of usage and cleaning logs for then sampling rooms were reviewed – no issues were noted.

Finished Product Warehouse

The finished product area was on the ground floor and had locations for quarantine, released and rejected materials, as well as a retained sample store. The area was well maintained, in a clean and tidy condition and pest control measures were evident. Rejected finished product rooms were empty at the time of inspection.

The retained sample store logbook was reviewed and appeared to be accurate. In addition, a stability chamber, located within the retained sample room was opened and appeared to be in a good state of control – with contents clearly segregated and labelled.

Packaging Materials and Printed Media

The packaging materials and printed media were stored in the basement. There was a separate locked room for the printed media. The area was controlled to NMT 28°C. Procedure effective 01/03/2019 was in place and included a list of acceptance criteria and sampling quantities for these materials based on the ISO2859 sampling standard. The SOP stated that each packaging material was to be sampled "separately" but was silent on the need to document an effective line clearance between sampling each batch. This issue was raised as part of a deficiency.

Manufacturing

Gowning for the manufacturing and primary packaging areas involved removal of outdoor clothing and socks, then donning a overall and snood, facemask, facility socks and shoes. However, there was no requirement for beard covers for men with facial hair.

The manufacturing areas were controlled by the building management system to between 15°C and 25°C and at ~70% RH. The system was alarmed with respect to temperature and humidity, and manual readings were also taken, recorded in logbooks and batch manufacturing records as required. Differential pressure was monitored using manual magnahelic gauges. Each gauge had a unique identifier and was marked with the required operating range. Manual readings were taken twice daily and record in logbooks. A deviation was required if any differential pressure readings were outside the identified range. During the inspection the reading for gauge [redacted] (between male change area and corridor) was noted to be very close to the upper limit (-0.6 to -3.0); this was highlighted to the site and a deviation was raised and appropriate corrective action taken.

Within the manufacturing floor were various rooms including a dispensary, two gel preparation rooms, two medicine preparation rooms, a staging area, various storerooms, a wash bay, three encapsulation suites, four drying rooms, and rooms for capsule printing and inspection.

Approved raw materials were issued from the warehouse and received into an airlock prior to dedusting and placing into a staging room. The dispensary had separate entries for people and materials, with additional gowning requirements. There were two identical dispensing booths, each equipped with two balances attached to printers. The balances were subject to daily verification (at the specified minimum and maximum weights) and monthly calibration (linearity, precision and eccentricity), and these were recorded in logbooks with the printouts attached.

It was explained that excipients were always dispensed before APIs. Each API had its own dedicated scoop, whereas excipients used common scoops. Logbooks captured all dispensing and cleaning activities to a suitable level of detail. Solid materials were dispensed into double polythene bags, with the label placed between the two layers. Liquids were dispensed into stainless steel containers.

[redacted]

Medicines preparation was where the API and excipients were mixed to form the capsule filling solution. One of the two medicine preparation rooms was dedicated to the two potent molecules ([redacted]), though it was confirmed that this had only been implemented three months prior to the inspection. The other prep room was for multi-product use.

The encapsulation process was observed during the manufacture of [redacted].

[redacted] Whilst there was no immediate contamination concern it was evident from discussion that the use of the plastic tie wraps had not been fully risk assessed, for example the tie wraps were a product contact part but no consideration had been given to documenting and controlling the material of construction, they were not reconciled to ensure none had been lost into the batch, and were not inspected for damage post use despite them being subject to mechanical impact as the drums rotated. This was not raised a deficiency, but the site was encouraged to consider additional control and / or assess the feasibility of another method of attaching the lint free cloths.

Periodically the drums would [redacted] There was also an inspection room, used for 100% visual inspection and metal detection.

The IPQA room housed various items of test equipment such as balances, hardness testers, viscometer and an LOD tester. Calibration records for the [redacted] viscometer were seen.

Primary Packaging

The facility had capacity for [redacted] packaging lines, though only [redacted] were in place at the time of the inspection. The blister equipment was of a standard design, with PLC control and a camera system to detect missing and rogue capsules. Line [redacted] was observed during the packaging of a batch of [redacted] It was noted that the batch number and expiry date were included as part of the pre-printed text on the foil; it was explained that this was the case for a number of products, and the foil manufacturer was provided with the necessary batch-specific information with the reels delivered just in time for use in the packaging process. Other products had their batch coding applied on the blister line using individual character blocks which were set up by the packaging staff and verified before use by IPQA.

There was a small IPQA room used for leak testing of blisters.

Secondary Packaging

The secondary packaging area had a separate gowning process. The packing hall contained three cartonning lines, with shoulder-height barriers between them. One line was also set up for manual cartonning operations, and this was observed whilst packing [redacted] for [redacted] The completed blister strips from the primary packing line were collated into 5x10s and placed inside foil pouches which had been pre-coded with the batch number and expiry date. These were then heat-sealed and two pouches placed into hand-erected cartons together with a leaflet. The cartons were closed and tamper-evident stickers placed on each end, before being printed with batch-variable data. The finished cartons passed over a checkweigher before being placed into cardboard outers.

The pre-coding of the pouches and the online coding of the cartons were both recorded on the same page of the batch record, despite taking place on different days, and the format of the page did not make it easy to understand the sequence of events. The inspectors suggested that splitting the two separate events onto different pages may improve clarity.

The checkweigher was not subject to any challenge tests during a batch, so it was not clear whether a problem with the reject mechanism would be evident to the operators.

The automated cartonners were equipped with carton and leaflet feeders, and missing component sensors. Pharmacode readers were also evident, although no challenge tests were carried out to ensure that rogue componentry would be detected and rejected.

Line clearance within primary and secondary packaging was documented on the batch packaging records and carried out in accordance with the procedure for [redacted] effective 23/08/2025. Between batches of the same product, line clearance was carried out by production staff only. QA checked line clearance only between product changes. The lack of independent QA checks of all line clearance activities was not considered appropriate.

Also, the description of the line clearance process in the governing procure was generic in nature, not of sufficient detail, and did not specifically identify areas of concern. Similarly, the confirmation of line clearance as recorded in the BPR was not of sufficient detail with one check box covering multiple activities e.g. “check and ensure the cleanliness and condition of the change part, hopper, chute, brushes, guide”. In addition, training for line clearance personnel was classroom based and theoretical in nature; there was no documented practical or on the job training. These issues were raised as part of a deficiency

HVAC

There were 10 recirculatory AHUs supporting the manufacturing areas, and another 3 AHUs supplying the packaging floor. The manufacturing and primary packaging areas were designed to meet EU Grade D. The AHUs were monitored daily and the results captured in logbooks. Pre-filters were routinely changed every month, and medium filters changed every 2 years or when the ΔP reached the specified limit. The logbooks for [redacted] were seen; this supplied various parts of the manufacturing facility including the dispensaries, staging areas, corridor and airlock, tool room and the medicines preparation room.

[redacted] described the preventive maintenance of the AHUs, and [redacted] was for the PM of the dust collectors. Records relating to both operations were seen.

The environmental monitoring program was outlined in SOP [redacted], and comprised of settle plates, active air sampling and contact plates. Settle plates were exposed for [redacted] hours [redacted] per month. Active air samples of [redacted] were collected every quarter. Contact plates were prepared in house and also used on a quarterly basis. Finger dabs were also taken from the micro staff each quarter. Plates were incubated for [redacted] EM data was routinely trended, and species identification was required for any results above the action limits. The latest trend reports showed no excursions or adverse trends.

Purified water

The purified water system was located on the top of the building. Incoming municipal water was subject to pre-treatment, PW generation and distribution. Pre-treatment included filtration, activated carbon and UV sanitisation. Purification used RO-EDI technology. The resultant purified water was held in a [redacted] storage tank and circulated around a single distribution loop with 9 user points. The system was equipped with inline conductivity, temperature and flow meters, and was controlled through a PLC system. There was also a heat exchanger which maintained the loop below 25°C and was used to heat up to 80°C for one hour every quarter as a routine sanitisation measure. UV lamps were monitored and changed every [redacted] hours. Logbooks were used by the system engineers to record various parameters on a daily basis.

PW sanitisation and cleaning was outlined in [redacted] and it was a requirement that the production department were notified ahead of any such activities. The carbon filter and softener were periodically cleaned, and this was controlled by the PLC software. The SOP also described the periodic cleaning of the RO membranes and EDI unit. The sanitisation process was described in detail, and the records for the most recent routine sanitisation were provided. No issues were noted.

The PW plant was subject to calibration and maintenance by external vendors. The RO unit was calibrated every year, and the EDI every 6 months. The current calibration records for the two conductivity meters (one on the RO unit, and one post-EDI) were seen.

SOP [redacted] covered the sampling and chemical testing of water samples, with SOP [redacted] describing the microbiological testing of water. Separate samples were taken for micro testing, TOC, pH/conductivity and chemical testing. A [redacted] sample was taken for micro, of which [redacted] was used for membrane filtration testing using [redacted] agar. The PW user points were routinely sampled every two weeks, along with the post-tank and return loop points which were tested twice per week.

The 2024 trend report for purified water was provided. No excursions were noted, and all chemical and micro data was within specification. Alert and action limits were defined in SOPs and were based on [redacted] of the trend data.

Equipment Qualification

The [redacted], effective 08/04/2019 was reviewed. The site utilised periodic requalification (PRQ) in accordance with a schedule stipulated in the validation master plan or following significant change (assessed as part of the change control process). No issues with the procedure were noted. The PRQ schedule was reviewed, and items checked at random were found to be in line with the timeline stipulated in the VMP – no issues were noted.

Calibration

The [redacted] effective 01/10/2018, was reviewed. An annual schedule for calibration was generated, and this was controlled on a paper system. Each month a list was generated for engineering identifying what items were due that month. Adherence against the annual list was checked – no issues were noted. The critical instrument lists [redacted] was reviewed – no issues were noted.

The most recent calibration report for the gelatine make-up tank temperature probe ([redacted] was reviewed. According to the governing procedure, [redacted], effective 21/09/2018, the acceptable range for temperature probe calibration was 1% of the full range of the relevant sensor, however the acceptance limits detailed in the calibration records were +/- 1 °C against an calibrated rage of 60-85°C; the limits stipulated were therefore not in accordance with the governing procedure. This issue was raised as part of a deficiency.

Maintenance

The preventative maintenance procedure, [redacted] effective 21/12/2020 was reviewed. An annual schedule for maintenance was generated, and this was controlled on a paper system. Each month a list was generated for engineering identifying what items were due that month. Upon completion of maintenance activities, the paper list was annotated with an actual completion date, however the entries were not attributable to an individual as they were not initialled and dated. In addition, the process of annotating the list with completion dates was not described in the governing procedure. This issue was raised as part of a deficiency.

The adherence against the annual list was checked – no issues were noted. The most recent maintenance performed on encapsulation machine [redacted] completed on 10th October 2025 was reviewed – no issues were noted.

C7 Documentation

Most procedures and quality records were dual language, with an English translation next to the Vietnamese text in each section of the documents.

Procedures were generally assigned a two-year review date, and the period could then be extended for a further two years following a review if no changes were required (up to a maximum of 8 years total – initial 2 years period plus 3 x 2-year extensions). All SOPs viewed during the inspection were within their assigned period, with permitted extensions documented.

Batch Record Review

The procedure for batch review and release was [redacted] Specific duties were outlined for the checks performed by IPQA and QA, and there were standard checklists available for the BMR, BPR and QC data. Any omissions or errors were documented and notified to staff for attention. All relevant incidents, deviations or OOS had to be closed prior to batch release. Once all checks were completed, QA passed the documentation to the QA Head for the final batch decision. Following release, approved labels were attached to the pallets and the batch moved to the approved finished goods store.

Artwork control

The artwork control procedure was [redacted] and was applicable both to new artwork designs and changes to existing printed packaging. The customers would provide the original

artwork designs, and then Phil Inter Pharma would generate their own component code. Approved electronic files would be sent to the local packaging vendor and the resultant pdf sent round for review and approval. This step would include approvals from marketing, regulatory, production and QA. Following approval of the proofs, a copy would be sent to the vendor for samples to be generated, including shade cards. All routine deliveries of printed packaging were checked against the approved artwork as part of QC testing. Upon revision, the superceded version would be removed from use and the vendor requested to confirm destruction of their master artwork and any plates or moulds.

An example was seen (change control reference [redacted] relating to updates to the cartons and leaflets for the [redacted] products, both initiated by the customer in [redacted] In addition to the controls described in the SOP above, the remaining warehouse stocks of the existing components were identified and rejected to prevent further use.

It was noted that not all product leaflets and cartons used pharmacodes; this depended on the individual customer requirements. For those products which did have pharmacodes, their generation and use was described in [redacted] There was a central pharmacode log, with the next available code allocated whenever new artwork was created or revised. An example was seen for [redacted] for the [redacted] market, along with the carton supplier's shade card.

C8 Production

Capsule manufacture

Soft gelatine capsule manufacture was a standard process comprised of several stages. [redacted] See also Section C6.

Equipment cleaning

Procedure [redacted] entitled [redacted] covered various items of equipment such as bulk manufacturing tanks, hoses, sieves, containers and scoops. It also described the equipment cleaning processes in detail. After use, items were bagged or shrink wrapped and then transferred to the wash area for cleaning. The general approach to equipment cleaning used a combination of hot water, detergent solution, purified water rinse and compressed air.

The cleaning process for the medicine hold tank was reviewed in detail: the SOP required the tank to be [redacted] It was noted that the cleaning records for this equipment only captured the date of cleaning and the previous product details; the parameters required by the SOP were not recorded so it was not possible to demonstrate that the process was carried out consistently.

Cleaning validation

The cleaning validation procedure was [redacted] and incorporated both cleaning validation and verification. There were two types of equipment cleaning processes: batch-to-batch and product changeovers. Cleaning validation of product changeovers was based on a minimum of three batches and covered API residues, microbial load and detergent residues. Potent products were subject to cleaning verification at the end of every campaign (see below).

Worst-case (non-potent) products and the associated MACO values were calculated from a combination of solubility, PDE and potency data.

Visual inspection, swabs and rinse samples were used to evaluate the effectiveness of cleaning. Sampling locations were defined, and the SOP included helpful photographs. Swab solvents were specified for each product, and recovery studies were performed for different materials.

The results of a recent CV exercise following [redacted] manufacture were reviewed. The acceptance criterion was [redacted] per swab, and the stated LOQ was [redacted] All swab and rinse sample results were below the limit of detection.

Potent product manufacture

Two products were manufactured in equipment dedicated to potent molecules; these were [redacted] egarded as highly potent) and [redacted] . Both products required campaign working with cleaning verification performed after every campaign. [redacted] stated that these high potency products could only be manufactured in medicines prep room [redacted] and encapsulation room [redacted] It also stipulated that other products could not be manufactured elsewhere in the facility whilst potent products were being handled. Satisfactory cleaning verification was mandatory before the manufacture of other products could restart.

PDE values

There were multiple molecules handled on site, with PDE values ranging from [redacted] Most products were manufactured in multi-use equipment, and the PDE figures were used in determining worst-case products for cleaning validation. The lowest PDE molecule [redacted] was manufactured in general equipment rather than the potent area but was also subject to cleaning verification after every batch/campaign. The PDE reports for [redacted] were reviewed. The [redacted] data was provided by [redacted] data was provided by [redacted] The CVs of the toxicologists were satisfactory.

C9 Quality Control

The QC lab was located at Plant 1 (MHRA site number 15275896) which was located a short drive away from Plant 2 on the same industrial park. The QC department carried out the testing of starting materials, bulk products and finished products for both facilities. They also performed method validation, EM testing, purified water analysis and stability testing.

Incoming samples were booked in using logbooks and stored in designated cabinets whilst awaiting testing. The accompanying documentation included the warehouse receipt checks, material C of A and the sampling request form. Each sample was allocated an AR number to track its progress through QC.

Chemical Laboratory

The QC lab was divided into various rooms, such as a wet chemistry area, HPLC rooms, a GC room, balance room and various stores.

The sampling procedure [redacted] outlined the sampling plan and required quantities of each raw material, and this was reviewed in connection with a recent delivery of [redacted] (AR number [redacted]). This was a delivery of [redacted] containers from the approved supplier [redacted] The sampling SOP specified [redacted] from each container for identity testing, a further [redacted] pooled sampled for composite testing, and a [redacted] composite as a reserve sample. The [redacted] specification ([redacted] included 3 separate identity tests (RI, IR and density), with full pharmacopoeial testing on the composite including assay by titration and impurities by GC. The limit for Impurity A [redacted] was [redacted] It was noted that the [redacted] test was only carried out on the composite sample. The inspector explained that as this impurity had been implicated in several high-profile contamination incidents around the world, it was important to carry out the [redacted] test on every individual container in order to maximise the chances of detecting any contamination in a delivery. The same approach would also be required for any other raw materials that required [redacted] analysis (for example [redacted]

Primary reference standards were sourced from pharmacopoeial sources. In-house working standards were prepared from previously approved batches of starting material, and the qualification of one such standard [redacted]) was reviewed. The IR identification, LOD and assay were performed in duplicate and upon satisfactory completion a series of [redacted] vials of

working standard were then prepared. Each vial was allocated a one-month expiry date from the point of opening. The usage log indicated that [redacted] vials had been consumed and [redacted] remained in stock, and this was confirmed by examining the quantities in the standards fridge.

There were [redacted] HPLCs operating on [redacted] software, and an [redacted] GC which used [redacted]. All were standalone systems, with local PCs and individual UPS. It was stated that all data was backed up twice per month with the saved data stored offsite. A restore exercise was scheduled every 6 months.

On each PC, access to [redacted] was through generic logins depending on user role (QC, QA or Admin). Chromatographic software logon was by individual username and password; there were 3 user access levels (admin, user and supervisor) and the access rights for each level were clearly defined in SOP [redacted]

HPLCs underwent 3-monthly preventive maintenance and 6-monthly calibration. The records for uni[redacted] were reviewed. This included measurement of flow rate accuracy, temperature, detector linearity, wavelength accuracy, injector repeatability and carryover.

The method validation for the assay of [redacted] was inspected. This had been carried out under protocol [redacted] in June 2024, and comprised system suitability, specificity, accuracy, linearity, precision and solution stability. No issues were noted.

Microbiology Laboratory

The microbiologists prepared their media from commercially available dehydrated powders. The records for the preparation, sterilisation and growth promotion testing of a batch of [redacted] were reviewed with no issues noted.

Incoming test samples were recorded in a logbook, and a selection of water samples were chosen by the inspector and quickly located in the relevant incubator.

There were [redacted] autoclaves used for sterilisation, pre-programmed with 4 different cycles. Printouts from every cycle were retained along with samples of the temperature-sensitive tape used in the load. The Oct 2025 calibration record for the temperature probe in autoclave [redacted] was seen. A separate autoclave in another room was used to decontaminate samples post-testing.

The inner core of the lab contained a further changing room and airlock which led to two separate rooms. One was dedicated to sample handling and the other for inoculation. Both were Grade C areas and contained biosafety cabinets under Grade A conditions.

Stock cultures of the expected range of organisms were purchased as bioballs; these were ATCC traceable and supported by certificates of analysis.

Stability

Each stability study was defined in a protocol outlining the conditions, duration, time points and testing requirements. A master schedule was prepared each year showing all the studies in progress. From this master, monthly schedules were generated to inform QC of which samples required pulling and testing. Worksheets were used to capture the loading and pulling of samples throughout each study, and to reconcile the number of packs used. An example was reviewed for [redacted] The protocol showed that [redacted] blisters had been laid down in the 25°C/60% RH chamber, with [redacted] remaining at the time of the inspection. The samples were quickly located in the chamber and the quantities aligned with the documentation.

There were multiple stability chambers covering a range of ICH conditions. Temperature and humidity were monitored electronically with alarms generated in the event of any excursions. The data was printed and reviewed regularly, and the chambers were mapped every year.

OOS/OOT and laboratory incidents

Procedure [redacted] described OOS and OOT investigations, and applied to the testing of raw materials, in-process samples, finished products and stability samples. The SOP was highly detailed, including multiple flow charts, and was in line with published OOS guidance on phase I/II investigations, including scope for hypothesis testing.

There had been 3 OOS raised in 2024, and 8 in 2023. A number were selected for review:

Stability testing of [redacted] in March 2023 generated several low OOS assay and content uniformity results; it was noted that the first few peak areas were variable and then became stable later in the sequence. It was hypothesised that the HPLC needle required rinsing; this was carried out and a number of samples and standards reinjected where it was noted that all the peak areas then appeared to be more consistent. The initial sequence was invalidated, and a full reanalysis of all samples generated results that were within specification and closely aligned.

In June 2023 low OOS assays were seen for multiple pilot batches of [redacted]. These were all 36m stability time points under 30°C/75%RH conditions. No lab issues were noted during the investigation, and a retest confirmed the results. It was noted that samples stored under 25°C/60%RH conditions remained stable. The results were accepted as valid.

Stability testing of [redacted] batches of [redacted] in Oct 2024 resulted in low OOS assays at the 36m time point. No obvious lab errors were noted, and reinjections confirmed the initial results. Reanalysis of one batch by a second analyst gave the same results. It was concluded that the product could not support a 36m shelf life.

There was a separate procedure for laboratory incidents [redacted] . This was used for issues such as SST failures, poor peak shape, sample spillage or notable differences between duplicate samples. To date there had been 94 incidents raised in 2025. Most were due to SST failures, chromatographic problems or instrument errors.

C10 Outsourced Activities

Technical Agreements

The procedure for [redacted] effective 05/12/2020, was reviewed. Technical agreements were typically valid for 3 years but were sometimes valid for 5 years as agreed between contract giver and contract acceptor. A period of ±45 days from end of the validity period was allowed to approve a new version of the agreement. A template was included as Annex 2 to the procedure.

There were 64 agreements in place at the time of the inspection. Agreements [redacted] and [redacted] were reviewed. No issues were noted.

Contract QC Testing

Two contract QC laboratories were employed; both were located in [redacted]

[redacted] were used for AAS and ICP testing for metals, residual solvent testing and other specific tests such as GMO and pesticides.

[redacted] were used for any microbiological speciation work, and this would be carried out using PCR. A suitable contract was in place, which specified sample turnaround times.

C11 Complaints and Product Recall

Complaints

Customer complaints were described in procedure [redacted]. It was anticipated that complaints could be notified from various sources such as patients, healthcare providers, distributors, overseas partners/MA holders, or regulatory authorities. All complaints were to be acknowledged within 24 hours and forwarded to QA for processing. Complaint samples or photographs would be requested if not provided. All complaints were categorised as either substantiated or unsubstantiated and could be divided into service- or quality-related complaints. The potential impact was defined as either critical, major or minor, with escalating timelines for investigation and closure of the higher categories. There was also a process to evaluate the potential for falsified products.

Three complaints were raised in 2024 (none raised in 2023). One example was reviewed. A pharmacy in [redacted] reported one leaking capsule in a pack of [redacted]. No sample or photographs were provided, and a review of the batch documentation did not highlight any issues. The retention samples were examined, and no issues were noted.

Recall

Recalls were described in [redacted] A recall committee would be convened, and the process was under the direction of the Head of QA. The committee comprised a board member, the Heads of QA, production, QC, marketing and R&D, along with any customer representatives or QPs as necessary. The standard classifications (Classes I / II / III) were outlined, along with Class IV (Caution In Use) as per UK procedures, and the timelines for action were in line with expectations. Interactions with the UK MAH and MHRA were suitably described.

It was stated that there had not been any recalls from any markets to date.

There was a separate procedure ([redacted] for mock recalls, which were carried out every two years, typically using a Class II or Class III scenario. It was noted that there was no requirement to periodically use an out-of-hours test.

The most recent mock recall was conducted in Aug 2025 on a product supplied to the [redacted] market, and the batch was traced to multiple wholesalers and pharmacies. The associated correspondence indicated that the customers were required to quarantine and return all remaining stock to the [redacted] distributor, and then after completion of the exercise they were informed that it had been a mock exercise, and the product could once again be supplied. The inspector expressed concern that this could result in supply shortages if the product was the only batch in circulation. It was explained that traceability and reconciliation of the batch quantities, and ensuring the customer contact details remained valid, were sufficient to complete the mock recall exercise.

Returned Goods

The returns procedure was [redacted] and covered various potential scenarios such as incorrect deliveries, damages, complaints, expired goods and recalls. Any returned products would be segregated and labelled to prevent mix-ups with other stock.

Any goods with the potential to be returned to saleable stock would be examined for their physical condition (including security seals and outer boxes), remaining shelf life and whether there was documented evidence of storage conditions whilst out of the company's control. There was also an evaluation for potential counterfeit products. the default approach was to reject and destroy returned stock unless all the requirements could be met.

C12 Self Inspection

The procedure for self-inspection, [redacted] effective 18/02/2025, was reviewed. The procedure required 6-monthly audits to be performed (with a tolerance of ±1 month from target date) of a number of different business areas / departments. Two auditors who were suitably independent of the business area / department being audited were assigned to each audit. Auditors were required to be approved by the site quality head.

The self-inspection calendar was reviewed and was up to date. Any audit findings during the self-inspection were required to be closed out within 90 days and there were no overdue findings past their closeout date at the time of the inspection.

The procedure used predefined inspection checklists for each of the areas (engineering, general areas, warehouse, QA, QA and production). There was a statement in the procedure that ,"care must be taken to ensure that the use of checklists does not become too restrictive and not allow the areas of potential problems to be fully evaluated.", It was unclear how this was prevented as checklists were used each time, however it was noted that there was the provision in the procedure to record ad-hoc observations in addition to those areas listed on the checklists. It was recommended that the site give some thought to expanding the self-inspection program to include different types of inspection and not always rely on checklists.

The procedure required that self-inspection reports were provided to auditees with 7 days and that actions plans were identified within a further 10 days – however these timelines were not tracked. Actions arising were tracked as part of CAPA SOP. The self-inspection schedule as up to date. A list of approved auditors was available and the documented approval of auditor [redacted] was reviewed – no issues were noted.

C13 Distribution and shipment (including WDA activities if relevant)

The procedure for [redacted] effective 25/06/2025, was reviewed. The procedure covered export of product by road, sea and air. No issues were noted with the procedure and the checks in place pre- and post-loading of vehicles arriving at site to collect goods appeared to be comprehensive and well documented. In addition, adequate procedures were in place for the attachment and review of temperature dataloggers, reference [redacted] effective 17/03/2021, and for the preparation of despatch documents, reference [redacted] effective 09/07/2020. However, the logistics provider for road transport from the site was not subject to formal approval e.g. as an approved supplier and was therefore not subject to any formally document periodic performance review. This issue was raised as part of a deficiency.

Processes were also in place for the validation of transport routes and an example for transport to [redacted] was reviewed, reference [redacted] The validation utilised QRM principles to ensure worst case conditions were covered e.g. validation runs conducted in rainy and sunny seasons. No issues were noted with the procedure, however mean temperature for each temperature sensor had been shown graphically and was referred to as a trend – even though no trend was shown. The data would have been better represented in a table format. This was not raised as a deficiency but was highlighted to the site as potential improvement.

No validation of routes to the UK had yet been completed at the time of the inspection – no product had yet been shipped.

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

None

D3 Others

3.1 Quality risk management was not fully embedded into the quality system. Risk classification decisions were not always fully documented or justified, as evidenced by:

3.1.1 A temperature excursion for a delivery of [redacted] had been evaluated as having no impact, with no justification documented despite the maximum temperature of 44.8°C being outside the limits detailed in [redacted]

3.1.2 Change control [redacted] or the relocation of hot and cold spot temperature probes following temperature re-mapping of the warehouse, was classified as a minor change. However no justification for this classification was recorded.

3.1.3 No documented justification was provided in support of change controls that did not have an effectiveness check.

Reference: EU GMP 1.4 (xiii, xiv), 1.13

3.2 Documentation control and completion did not always meet the required standard, in that:

3.2.1 Not all competed records were attributable to an individual, as evidenced by:

3.2.1.1 Schedules for calibration and maintenance had been updated with handwritten completion dates, but the entries were not initialled and dated in line with good documentation practice.

3.2.2 Data transcribed from one record to another was not subject to a documented accuracy check, as evidenced by:

3.2.2.1 PV protocol ref [redacted] for [redacted] contained handwritten data which was transcribed to the corresponding validation report ref [redacted]. There was no defined responsibility for checking the accuracy of the transcribed data.

3.2.3 Roles and responsibilities for review and approval of GMP documents were not consistently defined or applied, as evidenced by:

3.2.3.1 The roles and responsibilities for the preparation of process validation reports described in the VMP, validation procedure and validation report were not aligned.

Reference: EU GMP 4.2, 4.8

3.3 Packaging controls were deficient, in that:

3.3.1 Checkweighers were not subject to any routine challenge tests, and so it could not be assured that non-compliant packs would be rejected.

3.3.2 Pharmacode readers were not subject to any routine challenge tests, and so it could not be assured that rogue packaging components would be rejected.

3.3.3 Line clearance practices did not meet the required standard. Procedures, records, and training were not sufficiently detailed to ensure the consistency and thoroughness of line clearance activities, as evidenced by:

3.3.3.1 Line clearance procedures did not include sufficient detail, and potential difficult to clear areas were not identified.

3.3.3.2 Line clearance training was oral classroom training only. There was no practical training or qualification process.

3.3.3.3 Completion of line clearance activities were confirmed within the BMR/BPR with a single check box which did not include confirmation of all steps described in the SOP.

3.3.3.4 Line clearance following sampling of incoming printed packaging items was not recorded.

Reference: EU GMP 2.11, 3.41, 5.50, 5.57, 5.59 (v)

3.4 Equipment cleaning processes and records were deficient, as evidenced by:

3.4.1 Equipment cleaning records did not provide sufficient detail to demonstrate that the processes had been carried out in accordance with written procedures. For example, flush periods and drying times were not recorded despite being described in detail in [redacted]

3.4.2 The volume of [redacted] detergent to be used in cleaning various items of equipment was not specified in [redacted]

Reference: EU GMP 3.36, 4.6, 4.8

3.5 The risks to quality of starting materials were not minimised, as evidenced by:

3.5.1 The excipient risk assessment [redacted] did not consider the history of contamination risks at a global level for materials such as [redacted]

3.5.2 The test to detect the toxic contaminant [redacted] was only carried out on composite samples of [redacted] This reduced the chances of detecting any contamination if it was only present in one container of a batch.

Reference: EU GMP 5.29
EU Guidance on the formalised risk assessment for GMP for excipients (2015/C 95/02) 2.4 (v)

3.6 Processes for the calibration of equipment were deficient in that the limits applied during the calibration of temperature probes were not in line with the limits described in the governing procedure, as evidenced by:

3.6.1 The SOP required a limit of ±1% of the operating range, however the limits used in the calibration of the [redacted] tank temperature probe were ±1°C.

Reference: EU GMP 3.41

3.7 Recall management was deficient, in that:

3.7.1 There was no requirement for an out-of-hours challenge to the recall process.

Reference: EU GMP 8.30

3.8 Recording of training was inadequate, in that:

3.8.1 Training of personnel following minor updates to SOPs was not recorded. Therefore, it was not possible to confirm that personnel were trained in the latest version of procedures.

Reference: EU GMP 2.11

3.9 Supplier approval practices were deficient, in that service providers were not always subject to formal approval, as evidenced by:

3.9.1 The provider of road transport for despatch of finished goods was not included on the approved supplier list and had not been subject to a formal qualification process.

Reference: EU GMP 7.5

D4 Comments

4.1 It was noted that the gowning requirements for the production facility did not consider the use of beard covers for men with facial hair.

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

The inspection findings were presented to the management team, who committed to providing a response in the allocated timeframe.

F2 Assessment of response(s) to inspection report

An acceptable response was provided on 11th Dec 2025. GMP certificates were issued for both premises.

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

and is acceptable for the products in question.

Names of Inspectors:

Lead Inspector: [redacted] **Date:** 12 Dec 2025

Accompanying Inspector: [redacted] **Date:** 12 Dec 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:	1
Other deficiencies this inspection:	9	Last Inspection:	15

(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):

[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