

Deficiency	Proposed corrective action(s)	Target date
<p>Major: 2.1 – Transportation was deficient in that:</p>		
<p>2.1.1 – It could not be demonstrated at the time of inspection that storage conditions for medicinal products were being maintained during transportation within the defined limits as described by the manufacturers or on the outer packaging. The use of uncontrolled ambient had not been validated and no risk mitigation measures considered.</p>	<p>Confirm the suitability of uncontrolled couriers (such as [redacted] and [redacted] to meet the storage requirements for medicines during transit.</p> <p>We will validate transit temperatures using [redacted] single use temperature sensor, as recommended by the supplier of our permanent temperature probes for accuracy, reliability, and quality of [redacted] that comes with the probes.</p> <p>We will send monitored shipments to 3 large urban centers, the English regions, north and south of Scotland, Wales and Northern Ireland, ensuring that we capture variations in mode of transport and the longest transit times.</p> <p>If the plan is approved in time, we will validate cold weather transit during February, aiming to capture data from transit during which the outside temperature is <2 Celsius. If not, cold weather validation will be completed in December 2024.</p> <p>We would then repeat these at intervals when temperatures in transit or at delivery are forecast to be above or below our validated extremes.</p> <p>If the temperature does exceed the set limits determined from the data gathered, we would impliment additional measures, such as thermal or chilled packaging, delaying dispatch, or shipping the consignment with a temperature-controlled courier.</p> <p>We will integrate the [redacted] with our sales software, to generate per order [redacted] when temperatures outside our validated limits occur at base or delivery address for orders containing medicines.</p> <p>The API will check every order for medicinal items product codes, if it finds any, it will check the high and low points of the next 72-hour weather forecast for</p>	<p>Cold weather validation: 28.02.24 / 31.12.24</p> <p>Hot weather validation: between 01.07.24 - 31.08.24</p> <p>weather stack API implementation: 31.05.24</p> <p>Thermal packaging validation (cold): 28.02.24 / 31.12.24</p> <p>Thermal packaging validation (heat): 31.08.24</p> <p>Updated training material: 31.03.24</p>

	<p>the delivery postcode.</p> <p>If these temperatures are outside our validated limits, an email will be sent to [REDACTED] to trigger manual intervention, and activation of the most appropriate of the controls above are implemented.</p> <p>This will be evidenced by forwarding the alert email to [REDACTED], with confirmation of the control taken.</p> <p>In addition, we will deliver face-to-face training for all warehouse and office staff involved with the processing of medicinal orders, once changes in how they are processed have been implemented.</p> <p>This updated information will also be included in the annual GDP training presentation given to all office and warehouse staff involved in GDP activities.</p> <p>We will also update the eLearning courses to reflect the new information and higher level of detail in our related procedures, this will ensure new staff receive the correct information.</p>	<p>Updated training given to all relevant staff: 31.05.24</p>
<p>2.1.2 – No route risk assessments had been performed for small orders using courier services.</p>	<p>An updated route risk assessment will be conducted and drafted to reflect the proposed actions above once the validation exercise has been completed and the transitional period of sending via unvalidated, uncontrolled couriers is over.</p> <p>These documents will include consideration for controlled and uncontrolled couriers for both large and small orders, and the controls put in place to ensure storage conditions are met during transit.</p> <p>We aim to have these in place in line with the weather stack/API being implemented before 31.05.24 and will review them again after subsequent temperature validation to ensure accuracy.</p>	<p>Initial review and draft: 31.05.24</p> <p>Subsequent review: 31.10.24</p>

<p>2.1.3 – Presented technical agreements for controlled ambient transportation only considered water for injection, and not other medicines being transported such as Naloxone.</p>	<p>We have supplied a comprehensive and complete list of medicines stocked and their storage conditions to [REDACTED] to be included in the technical agreement.</p> <p>They have confirmed receipt of the TA form, but I am awaiting approval from their RP for the finalized document.</p> <p>As such, the submitted TA form and email correspondence confirming its receipt have been included as email attachments to our inspection response.</p>	<p>31.01.24</p>
<p>Other: 3.1 – The quality management system was deficient in that:</p>		
<p>3.1.1 – Presented procedures were ambiguous and did not fully reflect the operations described at the time of inspection. This included but was not limited to; 8.4 complaints, 8.5 recalls and 5 temperature monitoring.</p>	<p>All procedures have been reviewed, where applicable more detail has been added to allow for the full and accurate description of operations.</p> <p>As such, the following procedures are included as email attachments as part of our response:</p> <ul style="list-style-type: none"> • 04.2 – good receiving, storage and stock control • 08.4 – service and product feedback • 08.5 – product recall <p>All procedures will be reviewed again and updated at each stage of the validation processes and regularly scheduled 6 monthly procedure reviews.</p>	<p>31.01.24</p>
<p>3.1.2 – There was no documented process for managing changes outside of the document approval process.</p>	<p>We believe the following bullet points show that our combined ISO:9001/ISO:14001/GDP management manual is sufficient in managing change control:</p> <ul style="list-style-type: none"> • There is the dedicated procedure for information control. • Updated procedure 4.2 – ‘goods receiving, storage and stock control’ states under ‘stores control’ that proposed changes to warehouse facilities that affect licensed products be discussed with the RP. • Updated procedure 4.2 – ‘goods receiving, storage and stock control’ has multiple amendments relating to the storage requirements of medicines stocked. • Procedures are in place to control licensed product non-conformance and potential falsified medicines. 	<p>31.01.24</p>