

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER CDER/OPQ/OPMA/ Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPMABLAinspection483Responses@fda.hhs.gov		DATE(S) OF INSPECTION 03/16/2026-03/27/2026	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Pontus Rundström, Site Head, Operations		FEI NUMBER 3003347293	
FIRM NAME Q-Med AB	STREET ADDRESS Seminariégatan 21		
CITY, STATE, ZIP CODE, COUNTRY Uppsala, Uppland, Sweden, SE-75228	TYPE ESTABLISHMENT INSPECTED Drug Substance and Drug product Manufacturer		
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM, WE OBSERVED:			
OBSERVATION 1 The firm's contamination control strategy does not provide adequate assurance that (b) (4) are consistently contained within the upstream drug substance (DS) manufacturing areas. Deficiencies in procedures for handling (b) (4) containment breaches and controlling personnel flow create a risk of (b) (4) transfer to downstream DS and drug product (DP) manufacturing suites. A. Your procedures for managing breaches of (b) (4) containment are inadequate. The Class (b) (4) Microbiological Safety Cabinets (MSCs) are your (b) (4) containment for the (b) (4) handling of (b) (4). However, your procedures (including QMS-12492 and QMS-12331), do not require the documentation of (b) (4) failures (e.g., (b) (4)). This failure to record containment breaches prevents your firm from tracking, trending, or assessing the potential impact of (b) (4) on any given batch, making it impossible to ensure that containment was maintained during manufacturing. B. Your firm does not require personnel to shower after working in the upstream (b) (4) handling suite before moving to other manufacturing areas. SOP QMS-8836 requires only a change of outer garments. Your justification for not requiring a shower, (documented in MA-38919), is based on the assumption that the MSCs provide total containment. However, your risk			
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FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS

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assessment is flawed as it relies on an unverified assumption of containment, creating a risk of (b) (4) transfer via personnel's hair and skin. C. Your facility design and personnel flow procedures create a direct pathway for cross-contamination between (b) (4) handling and aseptic processing areas. According to QMS-15314, personnel working in both the upstream DS suite and the aseptic DP suite use the same changing rooms (b) (4) for gowning into and de-gowning from their cleanroom base layers. This practice allows personnel exiting the (b) (4) handling area to de-gown in the same physical space where personnel are gowning for entry into the aseptic core, creating a risk of transferring (b) (4) from the skin and hair of exiting DS staff to the clean garments of staff entering the DP suite. D. Your controls for personnel movement between manufacturing zones are inadequate to prevent the transfer of (b) (4) SOP QMS-8836 does not require a change of shoes when personnel move from the upstream "(b) (4)" area (Room (b) (4) to the downstream "(b) (4)" and "(b) (4)" areas. Instead, the procedure relies solely on the (b) (4) decontamination of shoes with (b) (4). Relying on a sporicidal spray as the only control for a high-contact surface like shoes is insufficient to prevent the tracking of (b) (4) from the upstream suite to downstream DS and other shared manufacturing areas, compromising the segregation between these zones.			
OBSERVATION 2			
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate aseptic techniques during aseptic filling setup for (b) (4) (b) (4) DP. Specifically,			
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A. Sterilized indirect product-contact parts including stopper (b) (4) bowl, (b) (4) for (b) (4) bowl, stopper chutes, (b) (4), stopper track, (b) (4), and utensils such as tweezers are removed from the (b) (4) and exposed to the Grade C environment outside the (b) (4) prior to the loading and installation of the parts inside the Grade A (b) (4). B. During installation of the stopper (b) (4) bowl, the operator touched the (b) (4) near the rim of the bowl with the non-sterile (b) (4). The (b) (4) of the rim of the stopper (b) (4) bowl is designed to (b) (4) the stoppers, therefore it is an indirect product contact surface. C. While installing stopper parts (stopper chute and stopper tracts) inside the (b) (4), the operators blocked first air over the exposed sterile surfaces of stopper (b) (4) bowl with the non-sterile (b) (4). D. At the start of the filling the operator removed the fallen vials from the (b) (4) using (b) (4) and blocked first air to the (b) (4). E. During the cleaning and disinfection of the (b) (4) prior to assembly and (b) (4) (b) (4) treatment, operators simultaneously (b) (4) (b) (4) thereby exposing the Grade A environment to Grade C conditions. Additionally, operators wearing Grade C gowning and face shields inserted their heads and upper bodies into the (b) (4). Furthermore, operators failed to demonstrate the slow, deliberate movements required by Cleanroom Aseptic Practice procedure (QMS-12386), while performing (b) (4) operations.				
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OBSERVATION 3 The environmental monitoring program is not adequate to ensure that the manufacturing areas for (b) (4) DS and DP are maintained in a state of microbial control. Specifically, A. The environmental monitoring surface sampling plan for the Grade A (b) (4) is inadequate. As detailed in procedure (QMS-12425 Form for batch-bound sampling of (b) (4) (b) (4) the plan fails to require sampling of critical product-contact and adjacent surfaces, such as the (b) (4), stopper bowl, or stopper chute, after batch production. B. The viable air monitoring program for the Grade A (b) (4) is inadequate in its timing and location of sampling. According to procedures (QMS-12425), monitoring begins only at set-up or filling, failing to continuously assess the environment immediately after (b) (4) decontamination. Furthermore, sampling is confined to the filling station and does not include other critical areas of activity, such as the (b) (4) C. The (b) (4) in the (b) (4) used for the manufacture of (b) (4) drug product are not sterilized. Procedures (QMS-12625 Batch related sampling and assessment manufacturing line (b) (4) and QMS-1540 Instructions for microbiological environmental controls) only describe sanitization of (b) (4) with (b) (4) not sterilization. The (b) (4) are used for approximately (b) (4) batches (b) (4) without sterilization. D. The incubation procedure for environmental monitoring plates (QMS-1540, Instructions for microbiological environmental controls) is not optimal for mold recovery. The initial (b) (4)			
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temperature incubation (b) (4) °C for (b) (4) before a (b) (4) temperature step (b) (4) °C for (b) (4) (b) (4) may inhibit the growth of some mold, potentially leading to their non-detection. E. The anaerobic environmental monitoring program is inadequate because it fails to monitor for potential anaerobic contaminants during at-risk, (b) (4) inoculation. According to the procedure (QMS-10309, Instructions for environmental control in premises with regard to (b) (4) (b) (4) anaerobic environmental monitoring is conducted only after production is complete and after the safety cabinets have been decontaminated with (b) (4) . This post-process, post-decontamination timing is not representative of conditions during (b) (4) handling steps and is therefore not designed to detect anaerobic contaminants when it is most likely to occur. F. The governing environmental monitoring SOP, (QMS-8071, Microbiological Environmental Monitoring, Cleanroom Manufacturing Line (b) (4) establishes alert and action limits based on total microbial counts and does not define a separate, more stringent limit for the recovery of mold. According to this procedure, a deviation investigation (which includes corrective actions such as cleaning and re-sampling) is initiated only when the total microbial count action limit is exceeded. The recovery of mold at a level below this limit does not require corrective action.			
OBSERVATION 4 Procedures designed to simulate aseptic processes are inadequate to assure the sterility of the drug product. A. Vials that are exposed during media fill interventions are excluded/omitted from incubation; therefore, the aseptic process simulation does not adequately evaluate the sterility of the full manufacturing process (including interventions). The intervention list for media fills (QMS-			
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12916), contains a column titled "Exposed vials in the (b) (4) shall be discarded after intervention." For numerous corrective interventions, this column is marked "Yes", mandating the disposal of vials. Examples include: - Intervention #205: "Wipe spill. Remove broken glass in the (b) (4) " - Intervention #214: "Open/correct the (b) (4) " - Intervention #502: "Wipe up spill. Remove broken glass in the (b) (4) " - Intervention #505: "Tipped over vial on the (b) (4) Wipe up spilled product on the (b) (4) " The procedure for validating aseptic processes (QMS-12184) permits this practice B. A smoke study of the Filling Line (b) (4) shows that when (b) (4) of the (b) (4) is (b) (4) smoke is seen coming out of the (b) (4) with turbulence and rising into the Grade C area, suggesting the (b) (4) is not maintaining proper containment during (b) (4)				
OBSERVATION 5 The firm's visual inspection is inadequate to ensure that the visual inspection process is under a state of control and that recurring deviations are effectively investigated or corrected. A. Your firm's procedure for 100% visual inspection categorizes rejected vials only into the following categories: Critical, Major, and Minor. Details for specific defect sub-categories (e.g., cracks, scratches, damaged caps, poor grooving) are not recorded or trended. A change control to implement specific sub-categories (record CC-482203) was not implemented until March 2026, which prevented your firm from adequately investigating and identifying the sources of all prior recurring manufacturing defects.				
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B. Between October 2024 and February 2026, (b) (4) out of (b) (4) manufactured batches of (b) (4) DP exceeded the total defect acceptance limit of (b) (4) %, established in your procedure QMS-14189. Out of (b) (4) batches, (b) (4) had a defect rate over (b) (4) % and (b) (4) batches has a defect rate over (b) (4) %. Examples of batches with exceptionally high total defect rates include: Batch (b) (4) (August 2025): (b) (4) % total defect rate. Batch (b) (4) (September 2025): (b) (4) % total defect rate. Batch (b) (4) (January 2026): (b) (4) % total defect rate. C. Your corrective actions have been ineffective at addressing recurring manufacturing defects. Corrective actions (CAPA 456501 Replacement of critical (b) (4) components and CAPA 457666 Clarification of (b) (4) procedures) were implemented on February 6 and February 23, 2026, respectively. However, all (b) (4) batches manufactured in February 2026 after the implementation of CAPA 456501 continued to exceed the (b) (4) % defect rate.				
OBSERVATION 6				
Your firm's cleaning and disinfection program is inadequate to decontaminate (b) (4) (b) (4) in drug substance and drug product manufacturing facilities and to address the risk of microbial contamination in controlled manufacturing environments. Specifically, A. Your cleaning log documentation is deficient because it fails to demonstrate that cleaning and disinfection are performed according to established procedures. Your practice of using a single log entry for multiple rooms is inadequate, as it does not record room-specific times or, most				
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critically, the actual contact times achieved for the disinfectants. This omission makes it impossible to verify that validated contact times were met. B. The material transfer procedures did not require validated "minimum wet contact times" to be maintained for the material transferred into the classified area. Your procedure for the (b) (4) transfer of materials into classified areas, (QMS-15314 "Gowning Procedures and (b) (4) (b) (4) – Manufacturing Line (b) (4) specifies the use of (b) (4) for the routine disinfection of materials. Furthermore, your material transfer procedure requires only that the material be allowed to "air dry for at least (b) (4) " after wiping with (b) (4) . This procedure does not specify a validated wet contact time. C. The frequency of cleaning with sporicidal agent (b) (4) (only qualified (b) (4) sporicidal agent) is inadequate to control (b) (4) contamination in a facility dedicated to manufacturing a product from a (b) (4) microorganism. This deficiency is demonstrated in the cleaning schedules for both external and internal staff: i. External Contractors: The routine facility cleaning program (QMS-1911) mandates the use of the sporicidal agent (b) (4) (b) (4) ii. Internal Personnel: The cleaning routine for manufacturing staff (QMS-13901) specifies that (b) (4) is used for (b) (4) cleaning (b) (4) (b) (4) D. The disinfectant efficacy study ("MA-35471 Report, surface challenge testing of biocides, production line (b) (4) approved December 9, 2020), does not adequately support the			
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effectiveness of (b) (4) to remove (b) (4) from all representative manufacturing surfaces. The study tested a limited set of surfaces and failed to include other critical materials of construction such as (b) (4) in the DS and DP manufacturing. E. The effectiveness of (b) (4) to inactivate (b) (4) (report MA-35587, Effect of (b) (4), has not been demonstrated for all manufacturing surfaces. The study tested a limited set of surfaces and failed to include other critical materials of construction such as (b) (4) and (b) (4) used in DP manufacturing, which are cleaned as part of (b) (4)			
OBSERVATION 7			
Your firm's quality system is inadequate because the Quality Unit does not ensure control over material status and final product disposition, resulting in the use of unreleased materials for manufacturing and the distribution of incorrectly labelled drug products.			
A. Not all (b) (4) DS batches are withheld from use until the lots have been fully released by the Quality Unit. Multiple (b) (4) DS batches have been partially released and manufactured into DP batches prior to being released by the Quality Unit. A few examples include: - DP batches (b) (4) manufactured for comparability studies. - DP batches (b) (4) manufactured for PPQ. - DP batches (b) (4) manufactured for analytical transfer submissions to (b) (4) B. Upon reviewing your labeling procedure it was discovered that two (b) (4) drug product batches had labelling errors.			
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i. A deviation (DEV-440958), initiated on May 2, 2025, documents a labeling error for drug product batch (b) (4). On the (b) (4) vial labels, the lot number and expiration date were transposed. The investigation identified the root causes as an "inadequate process/procedure" and "human error," as operators failed to verify the correct placement of the information on the label. Although the error was discovered during a QA review, the Quality Unit documented the product decision as "Accepted." The batch, with transposed information on the vial labels, was subsequently approved for release and distributed to (b) (4) after the subsidiary accepted the deviation. ii. A deviation (DEV-433408), initiated on March 4, 2025 documents the erroneous labelling of drug product batch (b) (4) with an incorrect expiration date. An incorrect manufacturing date (b) (4) was used for calculation instead of the correct date (b) (4). This resulted in the product being labeled with an expiration date of (b) (4). The root cause was identified as "inadequate procedures for verifying the documented manufacturing date". Despite this erroneous labelling, the QA Manager's final assessment states, "Batch (b) (4) has been approved for release in connection with this event," and the batch was distributed to (b) (4) after the customer agreed to the (b) (4) shelf life.				
OBSERVATION 8 Your firm's quality unit has failed to maintain adequate oversight, written documentation, procedural adherence, and document control. Specifically,				
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER CDER/OPQ/OPMA/ Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPMABLAinspection483Responses@fda.hhs.gov		DATE(S) OF INSPECTION 03/16/2026-03/27/2026	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Pontus Rundström, Site Head, Operations		FEI NUMBER 3003347293	
FIRM NAME Q-Med AB	STREET ADDRESS Seminariégatan 21		
CITY, STATE, ZIP CODE, COUNTRY Uppsala, Uppland, Sweden, SE-75228	TYPE ESTABLISHMENT INSPECTED Drug Substance and Drug product Manufacturer		
A. Written procedures are either not followed or lack comprehensive details to ensure adequate control of the manufacturing process. i. On March 16, 2026, during a walkthrough of the warehouse (Building # (b) (4)) an open case containing the raw material (b) (4) was observed where the individual containers were not labeled to indicate their quality status. Although the outer case was identified with an internal "Q-MED" status label, the (b) (4) bottles within the open case lacked any such labeling. This lack of individual container identification creates a risk of mix-up in manufacturing operations -should a bottle be removed from its parent case. It was noted that your firm initiated a deviation (DEV-485584) to address this issue during the inspection. ii. During the manufacturing of DS lot (b) (4) a (b) (4) hose connected to a (b) (4) bag ruptured during the (b) (4) step. Investigation revealed that the rupture was caused by (b) (4). A review of the governing batch record, (DS (b) (4) line (b) (4) QMS-14263, version 9.0) confirmed that the procedure fails to instruct the operator to adjust the (b) (4) to the correct setting prior to initiating the (b) (4). This lack of a specific, verifiable control step resulted in equipment failure. B. The document control is inadequate. Specifically, multiple identical copies of the shipping form are printed as part of the batch documentation to accommodate shipments to multiple destinations. This practice allows operators multiple copies without traceability.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Madushini N. Dharmasena - S Digitally signed by Madushini N. Dharmasena - S Date: 2026.03.27 11:36:31 -04'00' Olumide A. Martins -S Digitally signed by Olumide A. Martins -S Date: 2026.03.27 11:29:49 -04'00'		EMPLOYEE(S) NAME AND TITLE (Print or Type) Madushini Dharmasena, Ph.D., Senior Pharmaceutical Quality Assessor Olumide Martins, Ph.D., Pharmaceutical Scientist Jun Liu, Ph.D., Senior Biologist Qibing Zhou, Ph.D., Pharmaceutical Scientist
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Uppsala, Uppland, Sweden, SE-75228	Drug Substance and Drug product Manufacturer		
C. Your change control management system is not adequate and written procedures for change control are not followed, resulting in overdue changes and inaccurate records. Specifically, i. A review of your change control (CC) records revealed that 56 of 72 active changes initiated between August 2023 and December 2025 were past their target completion date. These records were not completed, nor were their timelines formally extended as required by your procedure QMS-7027 (work instruction for change control requests and change controls). Multiple change controls and their associated action items remain open long after their established target dates. Examples include: - CC 435213: Open past its May 15, 2025 due date. - CC 387929: Open past its June 30, 2025 due date. - CC 373511: Open past its July 31, 2025 due date. - CC 413980: Open past its October 29, 2025 due date. ii. Change control records are not updated to document notable alterations to the original change control. For example, CC 423647 was initiated to manage the transport and storage of (b) (4) at (b) (4). The plan was later changed to store the material (b) (4), however, the parent change control was not updated to reflect this significant change in scope. Although a related change control, CC429561, notes that storage at (b) (4) will not be performed, the change in scope regarding the transport of (b) (4) was not addressed			
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EMPLOYEE(S) NAME AND TITLE (Print or Type)			
Madushini Dharmasena, Ph.D., Senior Pharmaceutical Quality Assessor Olumide Martins, Ph.D., Pharmaceutical Scientist Jun Liu, Ph.D., Senior Biologist Qibing Zhou, Ph.D., Pharmaceutical Scientist			
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D. The written stability testing program is not followed and is not adequate to ensure that stability samples are tested at the required intervals. Specifically, Stability testing was not initiated for multiple drug substance and drug product batches within the timeframes required by your written procedures, (QMS-1200 Instructions for Sustainability Studies and QMS-1226 Instruction for Post Market Verification). These procedures require that assays be started within (b) (4) of sample withdrawal. However, significant delays were documented for various reasons. Examples include: i. Inadequate Resource Planning: Deviation reports (#394424, #424906, and #430072) document that stability testing was delayed due to an "insufficient analysis plan," specifically noting there were no available analysts to perform the required tests when they were due. ii. Lack of Materials and Certified Personnel: A deviation report (#455512) indicates that the (b) (4) analytical method for a stability time point could not be performed because a critical material, (b) (4), was unavailable and certified analysts were unable to perform the test. iii. Procedural Readiness Deficiencies: A deviation report (#459944) notes that LD₅₀ potency stability tests for multiple drug substance and drug product batches were delayed by 29 to 213 days. The root cause of the deviation was attributed to incomplete method validation for the LD₅₀ potency assay, such that it was impossible to perform the scheduled stability test.			
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OBSERVATION 9 Components and raw materials are not adequately tested and approved prior to their use in manufacturing. A. Your firm does not perform sterility testing on incoming lots of stoppers. Specifically, your firm relies on the supplier's Certificate of Analysis (CoA) to ensure the sterility of the (b) (4) (b) (4) Stoppers (b) (4), received from (b) (4) without performing its own sterility testing to verify the supplier's results. According to the firm's internal specification document, (QMS-12206, Justification of Specification), the rationale for sterility testing on incoming stoppers states, "Can not be tested, controlled during audit". While a bacterial endotoxin test is performed on a sample of stoppers from each lot, this test does not confirm the sterility of the component. Consequently, the sterility of the stoppers is accepted based solely on the supplier's validated process and documentation. B. Your firm failed to prevent the use of raw materials in manufacturing operations prior to their release from quarantine status. Specifically, the completion date for the drug substance manufacture of batch (b) (4) was February 25, 2021; however, the (b) (4) (batch (b) (4) which was used in the manufacturing of this batch, was still in quarantine. However, this (b) (4) batch was approved by QA for use on February 12, 2021 before the final certificate of analysis had been issued. This practice was justified by QC as it was determined that the quarantined material could be used without significant risk. The final release date for (b) (4) (batch (b) (4) by QC was March 09, 2021.			
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OBSERVATION 10 There is a failure to investigate invalid assays. Specifically, the procedure for handling invalid assays, (QMS-15172 v.1.0, Trending of Invalid Assays in QC, effective date for this SOP is March 13, 2026), defines the condition for an investigation as the failure of two consecutive system suitability criteria for the same sample. Therefore this procedure does not ensure assay failures are adequately investigated when the assay failure rate reach as high as 50%. A review of laboratory data revealed multiple analytical methods with high rates of invalid results that did not result in an investigation per the firm's written procedure. Examples of analytical tests with high invalid rates for which no investigation was conducted include, but are not limited to: (b) (4), DS (QMS-14463): 53% invalid assay rate (b) (4) invalid tests out of (b) (4) - Bacterial Endotoxins, Gel-clot, DS in-process (QMS-1353): 43% invalid assay rate (b) (4) invalid tests out of (b) (4) - Potency determination with LD50 (b) (4) (QMS-10268): 43% invalid test sample frequency (b) (4) invalid samples out of (b) (4) (b) (4) concentration by (b) (4) (QMS-14625): 42% invalid assay rate (b) (4) invalid tests out of (b) (4) (b) (4) related impurities, (b) (4) (QMS-12468): 37% invalid assay rate (b) (4) invalid tests out of (b) (4) (b) (4) concentration by (b) (4) DS (QMS-12449): 35% invalid assay rate (b) (4) invalid tests out of (b) (4) - Molecular weight (b) (4) of (b) (4), DS (QMS-11907): 31% invalid assay rate (b) (4) invalid tests out of (b) (4) (b) (4) concentration, DS (b) (4) (QMS-10002): 27% invalid assay rate (b) (4) invalid tests out of (b) (4) - Potency determination with LD50, (b) (4) (QMS-10268): 24% invalid test sample frequency (b) (4) invalid samples out of (b) (4)				
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(b) (4) concentration, DP (QMS-8470): 23% invalid assay rate (b) (4) invalid tests out of (b) (4) (b) (4) concentration, DP (QMS-14438): 17% invalid assay rate (b) (4) invalid tests out of (b) (4) - Bacterial Endotoxins, (b) (4), DS/DP release (QMS-4197): 16% invalid assay rate (b) (4) invalid tests out of (b) (4)			
OBSERVATION 11			
There are discrepancies between the information included in the (b) (4) and the testing operations at the manufacturing facility. Specifically, The reference standards used for the (b) (4) method for the quantitative determination of (b) (4) are not included in the (b) (4). Upon review of SOPs (QMS-15037 and QMS-15190), it was discovered that special reference standards are used in the (b) (4) method(s) for the quantitative determination of (b) (4) for (b) (4) drug substance and drug product. However, the reference standards used for the (b) (4) method are different from those that are described in the (b) (4).			
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