**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 109 Holton Street<br>Winchester, MA 01890<br>(781)587-7500 Fax:(781)587-7556 | 7/28/2025-8/8/2025*<br>FEI NUMBER<br>3022897129 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brett J. Wood, Associate Vice President Quality & Technical Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hikma Injectables USA Inc. | 36 Stults Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Dayton, NJ 08810-1540 | Outsourcing Facility |

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**
Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your firm's procedure, Standard Operating Procedure SOPDTN15125, "100% Visual Inspection of Compounded Sterile Products," Revision 3.0, effective December 30, 2024, establishes a (b)(4)% reject rate threshold before initiating quality events for 100% visual inspection processes (Section 7.10.12):

1. A (b)(4)% rejection threshold allows nearly (b)(4) of manufactured units to be defective before triggering investigation. Your firm's procedures provide no rationale or scientific justification for the (b)(4)% reject rate threshold. The SOP fails to specify whether this threshold applies to total rejects (combination of Critical, Major, and Minor defects) or to individual defect classifications.

2. Standard Operating Procedure SOPDTN15125, "100% Visual Inspection of Compounded Sterile Products," Revision 3.0, effective December 30, 2024 indicates that if the (b)(4)% reject rate is exceeded, a quality event will be initiated. For batches that fail the first AQL inspection and that have not already been labeled, a (b)(4) 100% re-inspection of the entire batch is allowed. Your procedures also permit conducting a (b)(4) 100% visual inspection and (b)(4) AQL without investigating the root cause of the initial AQL failure.

3. Ketamine HCL batch# 250860010D was produced on 04/02/2025. Visual inspection of the

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Erik W Koester, Investigator<br>Rose L Jean-Mary, Investigator | X Erik W Koester Investigator Signed By: Erik W. Koester -S Date Signed: 08-08-2025 10:46:48 | 8/8/2025 |

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batch revealed a 24.4% rejection rate in which (b) (4) units were overfilled (a critical defect). The firm's AQL inspection passed with no defects noted. The firm's investigation (ERF-2025-065) detailed that the root cause was attributed to personnel. A classroom training was conducted for SOPDTN15120 (b) (4) Final Container Fill Task of the Compounding Process). Per the investigation, the overfilled syringes were discarded, and (b) (4) units were released by Quality on 05/02/2025.

**OBSERVATION 2**

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

On 07/29/2025, black discoloration was observed on the interior HEPA bracket of the (b) (4) Aseptic Processing Workstation (b) (4) ). The (b) (4) was located within Room 121-B and was being utilized in the sterility testing of the following: Ketamine HCL lot# 252050004D, Diltiazem HCL lot# 251910016D and Rocuronium Bromide lot# 252050002D.

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

The firm's procedure for collecting active viable air within the ISO-5 laminar airflow hood is not representative of the full duration of sterile production process. The firm will only collect (b) (4) of air within approximately (b) (4) and the (b) (4) production process within the laminar airflow hood lasts approximately (b) (4) . For example, the aseptic process for Ketamine HCL 50mg per 5mL Lot# 25150009D was initiated at (b) (4) on 06/10/2025. The aseptic process concluded at (b) (4) and the active viable air sample was only collected at 9:22am.

**OBSERVATION 4**

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

The firm's procedure for (b) (4) testing (SOPDTN15300) is deficient in that a (b) (4) can be (b) (4) and evaluated via a (b) (4) test for a total of (b) (4) times before an investigation is conducted. For example, Event Report Form (ERF) # 2025-067 was initiated on 04/16/2025 to document (b) (4) testing of Rocuronium Bromide 50mg/5mL (lot# 250780001D). Per the investigation, the (b) (4) was (b) (4) with (b) (4) and analyzed via the (b) (4) test. The test failed and a (b) (4) with (b) (4) was conducted, and a (b) (4) test was performed. The (b) (4) test failed and a (b) (4) with (b) (4) was conducted, and a (b) (4) test was performed. The (b) (4) test failed and a (b) (4) with (b) (4) was conducted, and a (b) (4) test was performed. The (b) (4) test failed and a (b) (4) with (b) (4) was conducted, and a (b) (4) test was performed. The (b) (4) test failed, and an investigation was initiated. The investigation revealed that a leak in the tubing that connected to the (b) (4) Testing Instrument was the root cause of the failed results. The (b) (4) was then tested again after the repair, passing results were achieved and the batch was released and distributed.

***DATES OF INSPECTION**

7/28/2025(Mon), 7/29/2025(Tue), 7/30/2025(Wed), 7/31/2025(Thu), 8/01/2025(Fri), 8/04/2025(Mon), 8/05/2025(Tue), 8/07/2025(Thu), 8/08/2025(Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."