DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	7/28/2025-8/11/2025* FEI NUMBER 3014413265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Millan M. Bhatt, Owner/Managing Director

FIRM NAME	STREET ADDRESS
Molecular PharmaGroup LLC	755 Central Ave Unit 2 Unit 4
CITY, STATE, ZIP CODE, COUNTRY New Providence, NJ 07974-1116	TYPE ESTABLISHMENT INSPECTED 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

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

The firm's ISO 5 (b) (4) Vertical Laminar Air Flow (V-LAF) hood (Equipment ID: MPG-065), located in ISO 7 Room #(b) (4), which is used for sterile filling of Ethanol 70% (v/v) into 5 mL syringes, lacks a magnehelic gauge to measure the differential pressure between the ISO 5 LAF hood and ISO 7 room. There is no assurance that potential contaminants from the ISO 7 room do not enter the ISO 5 V-LAF during routine sterile filling operations. Batches of Ethanol 70% (v/v), including, but not limited to, batches # MFG-PC004(B)-021-25 (BUD: 24SEP2025), MFG-PC004(B)-023-25 (BUD: 13DEC2025), and MFG-PC004(B)-025-25 (BUD: 22DEC2025), have been filled in the ISO 5 V-LAF and released for distribution.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Annet R Rajan, Investigator Amatul H Marium, Investigator Stephenie M Ortiz, Investigator X Stephenie M Ortiz Investigator Signed By: Stephenie M. Ortiz -S Date Signed: 08-11-2025 15:52:05	8/11/2025

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1) The firm's airflow visualization (smoke) studies do not simulate the following interventions, including, but not limited to, those listed below that have been included during the firm's Aseptic Process Simulations and which could occur during the sterile filling of Ethanol 70% (v/v) into 5 mL syringes within the ISO 5 V-LAF hood (Equipment ID: MPG-065):

   - While filling is underway, an operator steps out from the V-LAF, then introduces new materials into the hood, and steps back into the V-LAF.
   - Pause filling operations while an operator steps out from the V-LAF, introduces a new Sterile (b)(4) Transfer Accessory for Pharmacy Transfer Tubing (PTT) Set and a Sterile Pharmacy Transfer Tubing with (b) (4) Inlet, (b) (4) Pump Insert into the hood, replaces them and resume filling operations.

Additionally, the smoke studies are not conducted with the viable and non-viable air monitoring systems turned on to visualize the air dynamics when monitoring systems are operational during routine sterile filling operations.

2) The firm's environmental and personnel monitoring program is deficient for the following reasons:

   a) The firm does not adequately monitor the air quality during critical sterile filling operations of Ethanol 70% (v/v) into 5 mL syringes. On (b) (4), during the observation of sterile filling of Ethanol 70% (v/v), Batch No. MFG-PC004(B)-029-25, in the ISO 5 V-LAF hood (Equipment ID: MPG-065), we observed that viable air sampling is limited to (b) (4) samples collected from the (b) (4) (b) (4) (b) (4) sides of the V-LAF hood at the (b) (4) of filling operations. No additional air sampling is collected during the remaining approximately (b) (4) of filling operations within the ISO 5 V-LAF hood.

   b) No viable and non-viable particulate air sampling is performed during the sterile (b) (4) of Ethanol 70% (v/v) in the ISO 7 Room (b) (4) and no sampling of operator's gloved (b) (4) is performed (b) (4)(b) (4). On (b) (4), during the observation of sterile (b) (4) of Ethanol 70% (v/v), Batch No. MFG-PC004(B)-029-25, we observed that only (b) (4) surface plate samples

were collected from the stainless-steel table after completion of (b) (4)

3) Goggles used by operators during sterile (b) (4) and filling of Ethanol 70% (v/v) in the ISO 7 Room (b) (4) and ISO 5 V-LAF hood (Equipment ID: MPG-065), respectively, are not of suitable design to prevent shedding of particulates and other contaminants from personnel into the sterile process. On (b) (4) , during the observation of sterile (b) (4) and filling of Ethanol 70% (v/v), Batch No. MFG-PC004(B)-029-25, we observed operators wearing goggles with direct vent holes, which are open to the environment, along the top of the goggles.

4) The firm has not adequately qualified the (b) (4) (Equipment ID: MPG-078) that is used to sterilize components such as the stir bar and scissors (used during the formulation process) and the sampling grid of the (b) (4) Viable Air Sampler that is placed in the ISO 5 V-LAF during the sterile filling of Ethanol 70% (v/v). During the Performance Qualification (Document No: MFG-EQ078-PQ-00) of the (b) (4) conducted from 03-04 Feb 2025, the firm used a (b) (4) Biological Indicator (BI) (Lot#(b) (4)) which had a starting population of (b) (4) this lot of BI was also used during the sterilization of components used in the manufacturing of Ethanol 70% (v/v), Batch# MFG-PC-004(B)-023-25. There is no assurance that the (b) (4) achieves a (b) (4) reduction in bioburden to assure sterility since the BIs only have a starting population of (b) microorganisms. Additionally, the firm does not conduct population and identity verification of each shipment of each lot of BI received.

OBSERVATION 3

Written procedures are not established for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Specifically,

The firm has not established a written procedure for conducting Annual Product Reviews (APRs). Additionally, the firm failed to conduct Annual Product Reviews for approximately (b) (4) batches

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of Ethanol 70% Injection(v/v) manufactured in 2024 to evaluate quality standards and determine the need for changes in drug product specifications or procedures.

***DATES OF INSPECTION**

7/28/2025(Mon), 7/29/2025(Tue), 7/30/2025(Wed), 7/31/2025(Thu), 8/04/2025(Mon), 8/05/2025(Tue), 8/06/2025(Wed), 8/11/2025(Mon)

X Annet R Rajan
Investigator
Signed By: 2003076177
Date Signed: 08-11-2025 15:54:08

X Amatul H Marium
Investigator
Signed By: AMATUL H. MARIUM -S
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EMPLOYEE(S) SIGNATURE
Annet R Rajan, Investigator
Amatul H Marium, Investigator
Stephenie M Ortiz, Investigator

X Stephenie M Ortiz
Investigator
Signed By: Stephenie M. Ortiz -S
Date Signed: 08-11-2025 15:52:05

DATE ISSUED
8/11/2025

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."