DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	2/3/2025-2/5/2025
	FEI NUMBER 3015348439

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amay Mahajan , Director

FIRM NAME	STREET ADDRESS
Pious Laboratories Private Limited	57 Confectionery Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rangwasa, Madhya Pradesh, 453331 India	Control Testing Laboratory

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 I OBSERVED:

OBSERVATION 1

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically, your firm's Quality Unit did not identify the calculation error for the % Relative Standard Deviation during the Particle Size Distribution analysis performed on October 07, 2024, of the raw material, (b) (4) . This error was not identified during the review of the analytical data by QC, the verification by QA nor during the investigation conducted into the analysis.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate standards and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm does not have a validated formula nor a written procedure to properly calculate the % Relative Standard deviation (% RSD) which is an acceptance criteria for the analysis of Particle Size Distribution of your OTC drug products.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kayla V Sprague, Investigator

X Kayla V Sprague
Investigator
Signed By: Kayla V. Sprague -S
Date Signed: 02-05-2025
14:34:46

DATE ISSUED
2/5/2025