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	7/23/2026-7/31/2026*
	FEI NUMBER 3008243902

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Ramesh Babu Mattupalli, Vice President Corporate Quality Assurance

FIRM NAME	STREET ADDRESS
Aizant Drug Research Solutions Private Ltd.	Survey No. 172 - 173, Apparel Park Road; Medchal-Malkhajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 500100 India	Finished Human 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 I OBSERVED:

OBSERVATION 1

Procedures for the cleaning and maintenance of equipment are deficient regarding maintenance and cleaning schedules, including, where appropriate, sanitizing schedules.

Specifically, your preventative maintenance procedure does not include the frequency or requirement for (b) (4) shared production equipment that is used in the manufacture of multiple US products.

The following deficiencies were observed:

a) You(b) (4) Machine (b) (4) had scratches, dents, and divots with discoloration within the dents along the interior product contact surfaces.

b) The valves located on you(b) (4) (including but not limited to (b) (4) had dents where operators had to tap the valve to open for (b) (4)

c) (b) (4) had scratches all throughout the interior bowl and the removable parts have dents and scratches along the surfaces where your operators use (b) (4) to set the equipment loose and tighten the equipment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Damaris Y Hernandez, Investigator - GDUFA X Damaris Y Hernandez Investigator - GDUFA Signed By: DAMARIS HERNANDEZ -S Date Signed: 07-31-2026 02:37:21	7/31/2026

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OBSERVATION 2

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, your firm failed to conduct complete identity testing of all incoming containers of the following materials:

a) (b) (4), that is a compound active pharmaceutical ingredient in the manufacture of US product (b) (4) Tablets, for the presence of (b) (4) (b) (4) contamination.

b) (b) (4), that is used as (b) (4) wipe down of all product contact surfaces on shared equipment used in the manufacture of US products, for the presence of (b) (4) contamination.

OBSERVATION 3

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, what appears to be rust and water staining was observed along the ceiling and light fixture housing that is directly above your (b) (4) where in-process products are open and exposed during (b) (4) activities. The distance between the ceiling and the open bowl of the (b) (4) is less than 9 feet. This is a shared piece of equipment used in the manufacture of US products.

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*DATES OF INSPECTION

7/23/2026(Thu), 7/24/2026(Fri), 7/27/2026(Mon), 7/28/2026(Tue), 7/29/2026(Wed), 7/30/2026(Thu), 7/31/2026(Fri)

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