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	6/8/2026-6/12/2026
	FEI NUMBER 3033035639

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jayanta Kumar Mandal, Managing Director and CEO

FIRM NAME	STREET ADDRESS
APDM Pharmaceuticals Private Limited	Plot Number 775, 776 & 628, Village Sakodara, Taluka: Bavla
CITY, STATE, ZIP CODE, COUNTRY Ahmedabad, Gujarat, 382220 India	TYPE ESTABLISHMENT INSPECTED 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

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A) Your firm has not adequately qualified the operating parameter for the following equipment intended for the commercial manufacturing of (b) (4) Tablets USP (b) (4) mg:

i) (b) (4) (b) (4) (Equipment ID: AP/PD(b) (4) 002) was qualified at (b) (4) as per performance qualification, Doc No. AP/PQP/PD(b) (4) 005, Rev 01. The (b) (4) (b) (4) of (b) (4) Tablets USP (b) (4) (b) (4) mg requires this equipment using (b) (4) at (b) (4) for up to (b) (4)

ii) (b) (4) (Equipment ID: AP/PD(b) (4) 007) was qualified at (b) (4) (b) (4) without evaluating operating duration as per performance qualification, Doc No. AP/PQP/PD(b) (4) 012, Rev 01. The (b) (4) of (b) (4) (b) (4) Tablets USP (b) (4) mg requires this equipment to operate at (b) (4) for up to (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Karishma G Gopaul, Investigator	X Karishma G Gopaul Investigator Signed By: KARISHMA G. GOPAUL -S Date Signed: 06-12-2026 06:32:22	6/12/2026

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B) Your firm has not adequately qualified the operating parameters for (b) (4) (Equipment ID: AP/PD(b) (4) 006) intended for (b) (4) Tablets USP (b) (4) mg. The equipment was qualified at (b) (4) without evaluating operating duration as per performance qualification, Doc No. AP/PQP/PD(b) (4) 001, Rev 01. The (b) (4) Tablets USP(b) (4) mg (b) (4) requires(b) (4) at (b) (4) for up to (b) (4)

C) Your firm has not challenged respective sensors following the Counting Machine (Equipment ID: AP/PD/BOT/022-CM/01) and the Capping Machine (Equipment ID: AP/PD/BOT/022-CP/01) on the Bulk Packing Line (Equipment ID: AP/PD/BOT/022), during qualification to demonstrate that the sensors can adequately detect filling errors (such as, overfill and underfill of tablets) and defects (such as, not limited to, loose cap, no cap, and missing (b) (4) under the cap), respectively. This is the firm's only bottle filling line, intended for the commercial (b) (4) packaging of (b) (4)

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