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	6/29/2026-7/3/2026*
	FEI NUMBER 3016480976

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sumant Pilgaonkar, Senior Vice President

FIRM NAME	STREET ADDRESS
Rubicon Research Limited	Plot A-17, Special Economic Zone, Phase II, Industrial Area
CITY, STATE, ZIP CODE, COUNTRY Pithampur, Dhar, Madhya Pradesh, 454775 India	TYPE ESTABLISHMENT INSPECTED Drug 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, of adequate size and suitably located to facilitate operations for its intended use.

Specifically,

A) (b) (4) 122, which is listed as the equipment (b) (4) used in the manufacturing for (b) (4) mg strengths of (b) (4) Tablets, is not qualified. Only an installation qualification has been completed.

B) (b) (4) Machine (b) (4) with ID # (b) (4) 009 was moved from Room # (b) (4) (b) (4) to (b) (4) under Change Control CC/1501/26-007 requiring requalification of the equipment prior to its use in commercial manufacturing. Performance Qualification, as required by the change control, has not been completed.

C) Equipment qualification of equipment used in labeling and packaging operations of (b) (4) Tablets has not been completed. These include the following pieces of equipment:

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer X Jeffrey P Raimondi Consumer Safety Officer Signed By: Jeffrey P. Raimondi -S Date Signed: 07-03-2026 14:31:05	7/3/2026

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(b) (4)

OBSERVATION 2

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A) There is no procedure currently in effect for the cleaning of the (b) (4) #(b) (4) 122 (b) (4) used for manufacturing (b) (4) Tablets (b) (4) mg strengths.

B) There is no cleaning record which documents the step-by-step cleaning activities required during the cleaning of the product contact (b) (4) #(b) (4) 006, used for (b) (4) operation of (b) (4) Tablets. Procedure: SOP/EQP/1501/000707, Usage and Cleaning of (b) (4) Effective Date: 01-Dec-2025, Version: 1, lists specific cleaning durations for each stage of cleaning. There is no documentation to demonstrate the minimum cleaning duration for each stage was met.

*DATES OF INSPECTION

6/29/2026(Mon), 7/01/2026(Wed), 7/02/2026(Thu), 7/03/2026(Fri)

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