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	9/1/2025-9/5/2025
	FEI NUMBER 3025926685

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Shailendra K. Singh, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Ritsa Pharma Private Limited	Neovantage Park, Bldg.1800, Survey No 101,101/2 & 340, 1800 Genome Valley Road
CITY, STATE, ZIP CODE, COUNTRY Medchal Malkajgiri, Hyderabad, Telangana, 500078 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:
MATERIALS SYSTEM

OBSERVATION 1

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,

Your firm did not conduct appropriate testing to ensure that components received from your vendors are of the right quality, purity, and strength that they purport. For Example:

1. Your firm (b) (4) testing of active pharmaceutical ingredient containers and compares results against supplier COAs without first establishing supplier reliability.
2. Your firm samples materials only from the (b) (4) of containers with a (b) (4) scoop without testing throughout the container depth to establish material uniformity.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Pearl C Ozuruigbo, Investigator

X Pearl C Ozuruigbo
Investigator
Signed By: Pearl C. Ozuruigbo -S
Date Signed: 09-05-2025
03:04:32

DATE ISSUED
9/5/2025

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