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	3/20/2023-3/24/2023
	FEI NUMBER 3013353854

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind Thakker, Technical Director

FIRM NAME	STREET ADDRESS
Stallion Laboratories Private Limited	Gallops Industrial Park-Ii, Plot No.: D-4,5,6,17,18,19, Sarkhej-Bavla Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ahmedabad, Gujarat, 382110 India	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 WE OBSERVED:
Quality System

OBSERVATION 1

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

On 3/21/2023, we reviewed the (b) (4) Performance Qualification Report, Document No.: SLPL-II/PQR/(b) (4)/02-00, Approved: 12/04/2021. The review of the PQR disclosed that your firm used "(b) (4)" and validated the (b) (4) parameters to reach a range of(b) (4)%. Your firms current manufacturing batch record for (b) (4) Tablets USP (b) (4)mg,(b) (4)mg, (b) (4)mg and (b) (4)mg) has established (b) (4)parameters of(b) (4)-(b) (4)%.

Your firm failed to establish a justification with scientific rationale to perform the PQ of the (b) (4) (b) (4) using (b) (4) and validated different parameters than the one established in the manufacturing batch record of(b) (4) (b) (4)% of (b) (4)

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Marian E Ramirez, Investigator Alan A Rivera, Investigator	X Marian E Ramirez Investigator Signed By: Marian E. Ramirez -S Date Signed: 03-2 -2023 00:12:0	3/24/2023

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	3/20/2023-3/24/2023
	FEI NUMBER 3013353854

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind Thakker, Technical Director

FIRM NAME	STREET ADDRESS
Stallion Laboratories Private Limited	Gallops Industrial Park-Ii, Plot No.: D-4,5,6,17,18,19, Sarkhej-Bavla Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ahmedabad, Gujarat, 382110 India	Manufacturer

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

While performing inspectional walkthrough on 03/20/23 of Compression Room (b) (4) in production of (b) (4) USP(b) (4)mg tablets, Batch(b) (4) we observed that one of the operators collected a rejected capsule from the floor with his gloved hands. We continue to observe operations and approximately 5 minutes later one of the operators collected an in-process sample directly from the finished product (b) (4) with his gloved hands. Your firm failed to establish a sanitation procedure inside the manufacturing room to prevent contamination of finished product after an operator has touched the floor and is then assigned to collect an in-process sample.

X Alan A Rivera
Investigator
Signed By: 2003421109
Date Signed: 03-24-2023 00:12:38

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Marian E Ramirez, Investigator Alan A Rivera, Investigator X Marian E Ramirez Investigator Signed By: Mar an E. Ramirez -S Date S gned: 03-2 -2023 00:12:0	3/24/2023