DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/ORA/OPQO HQ, Room #2032 12420 Parklawn Drive Rockville, MD 20857 Email: ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	05/27/2024-05/31/2024
	FEI NUMBER 3009765202

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Pankaj Sharma, General Manager

FIRM NAME	STREET ADDRESS
Swati Spentose Private Limited	Plot No A-1/2102, 2103 and A-2/2120, Phase III, GIDC
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Vapi, Gujarat, 396195, India	API Non-Sterile Drug Substance 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) (WE) OBSERVED:

OBSERVATION 1

Employees are not given role specific training to perform their function.

Specifically,

As per SOP # QCD/0117/000, "Procedure for Review of Analytical Documents and Reviewer Qualification", the QC laboratory reviewer who reviewed the testing data needs to be trained and qualified to perform the review of the analyzed test however your firm failed to ensure that all Quality Control (QC) laboratory reviewers are adequately trained to review laboratory data for product release. For example,

A) Residual Solvents test by Gas Chromatography (GC) was performed on 02/14/2024 for (b) (4) (b) (4) USP, batch # (b) (4) The QC laboratory reviewer who reviewed the testing data was not properly trained and qualified to perform the review of the analyzed test.

B) Residual Solvents test by Gas Chromatography (GC) was performed on 09/26/2023 for (b) (4) USP, batch # (b) (4) . The QC laboratory reviewer who reviewed the testing data was not properly trained and qualified to perform the review of the analyzed test.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Ankur C. Patel -S Digitally signed by Ankur C. Patel -S Date: 2024.05.31 01:41:10 -04'00'	Ankur Patel, Investigator	05/31/2024

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Your firm failed to ensure that all Quality Control (QC) laboratory personnel perform product testing according to approved testing procedures. Over one hundred OOS/Incidents investigations have been concluded as human errors since Jan 2021 despite ongoing retraining and requalification of analysts. Human errors in the QC lab such as incorrect entry of the sample details into LIMS system, dilution error, preparation error, wrong weight error, weight transfer error etc. have occurred repeatedly since January 2021 (as shown in the table below) despite of corrective actions including awareness training, retraining and requalification of analysts.

Year Of evaluation	Number of Human errors	Total
2021	Incorrect entry	26
	Preparation error/Dilution error	39
	Error due to overlook	36
	Weighing error/weight transfer error	24
	Incorrect data path	12
2022	Error due to overlook	36
	Preparation error	41
	Incorrect entry	24
	Other error	28
2023	Error due to overlook	67
	Preparation error	21
	Transcription error	12
	Other error	10

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1. INC-01-23-0342was opened on 09/15/2023 to investigate OOS results for Water Content by KF for (b) (4) (b) (4), Lot # (b) (4). It was determined that the transfer of (b) (4) weight (a human error) was not properly performed by the QC Analyst. A similar incident was opened about 6 months ago on 03/30/2023 under INC-01-23-0145 to investigate OOS results for Water Content by KF for (b) (4), Lot # (b) (4) performed by the same QC Analyst. The corrective actions, including awareness training, implemented had proven to be ineffective.

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