DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, CDER/OC/DMPQ/ICT, HFD-325 Attn: Alicia Mozzachio 10903 New Hampshire Avenue Bldg. 51, Room 4234 Silver Spring, MD 20993 (301) 796-3206 Industry Information: www.fda.gov/oc/industry	4/27/2015-5/1/2015
	FEI NUMBER 3009250999

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. B.S.N. Reddy, Managing Director

FIRM NAME	STREET ADDRESS
Nosch Labs Pvt Ltd	Surveys No. 332, 333 & 335, Velimineedu Village, Chityal Mandal
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Nalgonda District, Telangana, 508114 India	API 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
Drug products failing to meet established quality control criteria are not rejected.

Specifically,

A) Analysts employed by your firm in 2012 repeatedly used PC administrator privileges within HPLC chromatographic software to alter acquisition dates on HPLC chromatograms ("Nosch HPLC Reports"). For three batches of (b)(4) API intermediate (b)(4)) manufactured as part of process validation study VAL/QA/PR/006A between 7-16 February 2012, and further processed into (b)(4) API batches (b)(4) , I observed the following within the associated electronic data and analytical documentation:

1. For at least 26 in-process HPLC analyses used to gauge progress of key (b)(4) steps, the HPLC chromatograms created by your analysts contain "Acquired Dates" ranging from 2/7/2012 to 2/14/2012, which are not contemporaneous with the "Acquired" dates listed for the corresponding electronic chromatographic data files, dated 1/26/2012 to 1/31/2012.

2. The dates documented on the In-Process Test Report forms from each in-process HPLC analysis of these three batches appear to agree with the dates listed in the corresponding batch manufacturing records and HPLC chromatograms (7-14 February 2012). The in-process sample numbers for these analyses (ranging from (b)(4) to (b)(4)) are found on the In-Process Test Report forms as well as in the "Sample ID" of each electronic chromatographic data file, resulting in sample numbers correlated to data sets with two different dates, for each of the 26 documented tests.

B. Throughout the course of this inspection, your Laboratory analysts repeatedly failed to provide explanations for

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	Steven D. Kehoe	Steven D. Kehoe, Investigator	5/1/2015

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observed discrepancies found in the analytical testing records of drug substance(b)(4) causing several delays in the inspection and limiting my ability to assess your firm's drug manufacturing operations and associated documentation.

1. On 4/29/15, during my review of(b)(4) API testing records, batch(b)(4) dated 2/14/2012, I observed five analytical balance weight printouts from sample weighing activities, alternating back and forth between varying paper type and ink quality, and printed over the time period from 09:25:50 to 16:45:34. Your Laboratory Supervisor admitted at the time of these weighing operations, there was only one analytical balance and printer (equipment ID NL-IV-QC-07) present for use in the laboratory. Your analyst responsible for these weighing operations was asked to explain the discrepancy multiple times, and did not provide an answer to these inquiries. On 4/30/15, the analyst was again asked to provide an explanation, but stated he could not remember what occurred to cause the weight ticket discrepancies.

2. On 4/30/15, during my review of(b)(4) API testing records, batch(b)(4) dated 2/22/2012, I observed five analytical balance weight printouts from sample weighing activities, alternating back and forth between varying ink quality, and printed over the time period from(b)(4) to 10:26:51. Additionally, during my review of testing records for batch(b)(4) 2/21-22/2012), I observed five analytical balance weight printouts from sample weighing activities, alternating back and forth between varying ink quality, and printed over the time period(b)(4) 2/21/2012 to 10:29:10, 2/22/12. Analytical balance NL-IV-QC-07 was used for all weighing activities. Your analyst responsible for these weighing operations was asked to explain the discrepancy multiple times, and did not initially provide an answer to these inquiries. Later the same day, the analyst was again asked to provide an explanation, but stated she could not remember what occurred to cause the weight ticket discrepancies.

OBSERVATION 2

Sufficient laboratory controls are not established to ensure electronic records used meet systems validation requirements to ensure they are trustworthy, reliable and generally equivalent to paper records.

Specifically,

A. For your Shimadzu LC2010CHT HPLC system NL-IV-QC-16 using LC Solutions chromatographic software,

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and your Shimadzu GC 2010 Plus GC system NL-IV-QC-02, using GC Solutions chromatographic software, responsible laboratory management failed to enable audit trails or equivalent activity logs during analysis of (b) (4) API and (b) (4) API intermediate process validation batches from 7-22 February 2012. No audit trails covering these dates were provided upon request during this inspection, and audit trails were found disabled upon review of these systems on 4/28/15. Your Quality Control management personnel admitted audit trails had not been enabled on these systems since they were qualified on site.

B. Your Vice President, Quality Control/ Quality Assurance admitted prior to the implementation of your firm's SOP IV/QC/GN/049A on 11/1/2014, which delineates a user role hierarchy on site with defined privileges and permissions, all users of these software systems were given equivalent permissions and had administrator privileges. During the inspection, a software service technician from Shimadzu (called on site to assist the firm in enabling audit trails on these systems) showed me how system administrators on LC Solutions software were allowed to modify or delete identifying sample information from electronic HPLC chromatograms.

OBSERVATION 3
Equipment used in the analysis of drug products is not qualified for its intended use.

Specifically,
Your stability chamber NL-IV-SC-01, which was subjected to a temperature- and humidity-mapping study (24 hour duration at 25°C/60% relative humidity, 30°C/65% relative humidity, and 40°C/75% relative humidity) during equipment qualification executed on 4/3/2014, was mapped only in "empty" conditions. The system was not mapped with any sample load, despite your firm's intentions to store API stability samples within this unit at a specified uniform temperature and humidity setting.

OBSERVATION 4
Procedures for the cleaning of equipment used in the manufacture of drug products are not established.

Specifically,
Your firm manufactures API intermediates, including (b) (4) within (b) (4)

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(b) (4) vessels on site (equipment identification numbers (b) (4) However, your firm has not performed residual recovery studies from (b) (4) surfaces to validate the effectiveness of your current cleaning procedures on the product-contact surfaces of these (b) (4) vessels. To date, your firm has only performed recovery studies within cleaning validation activities on (b) (4) surfaces. Additionally, your written procedure for cleaning validation SOP/IV/QA/GN/021A, does not include any stipulations to perform residual recovery studies on materials other than (b) (4) despite the use in production operations of (b) (4) (b) (4) vessels.

OBSERVATION 5

Procedures have not been established which validate the output or monitor the performance of manufacturing processes that may be responsible for causing variability in the characteristics of in-process material or drug product.

Specifically,

Analytical testing method (b) (4) Related Substances by HPLC used for analysis of (b) (4) (b) (4) API batches (b) (4) (b) (4) manufacturing completed on respectively) was not validated at the time these lots were analyzed via this method. Your firm did not complete analytical method validation for the above testing method until 13 July 2012. There is no assurance this method as performed by your analysts using analytical equipment on site provided consistent, accurate results capable of detecting potential variability in the analytical characteristics of these batches of drug substance.

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