DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	8/16/2016-8/26/2016* FEI NUMBER 3004610460

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Arjun Handa , Vice Chairman

FIRM NAME	STREET ADDRESS
Claris Injectables Limited	Chacharvadi Vasna
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ahmedabad, Gujarat, 382213India	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 WE OBSERVED:
LABORATORY SYSTEM

OBSERVATION 1

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

a) On 8/22/16 an analyst was observed conducting endotoxin testing on (b) (4) Injectable Lot # (b) (4) and Lot # (b) (4) Per the firm's SOP # (b) (4) QCD/018, titled, "Bacterial Endotoxin Test", the endotoxin samples are to be inverted 180 degrees to observe if there is gel formation on the bottom of the test tube. The analyst observed conducting the testing, was tilting the sample test tubes less than 90 degrees when obtaining test results on multiple test samples. The angle the test tubes were observed being tilted to was not sufficient to consistently indicate gel clot formation and show a positive result for the presence of endotoxin.

b) Laboratory media used for sterility testing is not labeled following SOP # (b) (4) QCD/014, titled, "Media Preparation" which states under storage of prepared media, that each media tube is to be stored with the media identification name, lot number and (b) (4) date. However, (b) (4) media is not identified using lot #, name, or date made or expiring. Several racks of test tubes containing (b) (4) for (b) (4) and used in sterility testing were observed sitting in the incubation room with no label affixed or identification marker of any kind showing traceability or identification of the media. Further, sterility samples prepared in the sterile testing area of the microbiology laboratory are loosely affixed

with a label that is easily detached and may be removed or lost and may in return compromise the identity and traceability of the sample.

c) Media plates generated from Environmental Monitoring/Sampling and personnel testing, that are to be read by the Auto Colony Counter, are wiped free of their identification label showing date, location and employee tested if applicable, prior to being placed in the Auto Colony Counter for reading. The recorded digital photo taken by the Auto Colony Counter, showing results and colonies counted, does not include plate identification in the photo and hence does not ensure traceability of results. Per SOP # (b) (4) QAD/037, titled, "Auto Colony Counter", plates are to be affixed with the proper label as described in SOP # (b) (4) QAD/037, titled, "Clean Room Monitoring". The plates observed being read did not have a label, and the discarded plates that had been already read were observed as not having a label.

OBSERVATION 2

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet appropriate statistical quality control criteria as a condition for their approval and release.

Specifically, samples collected for BET testing, per SOP # (b) (4)/QAD/032, titled, "Finished Product Sampling", are not collected in sufficient quantity to be representative of the final batch.

OBSERVATION 3

The use of apparatus not meeting established specifications was observed.

Specifically, the (b) (4) used during sterility testing has not been qualified for that purpose.

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PRODUCTION SYSTEM

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

a) SOP (b) (4) PRD/004 Clean Room Entry - Exit Procedure requires use of sterile garments prior to entry into the clean room area. However, you have not validated the number of cleaning and sterilization cycles through which the garments can be processed and are relying on the supplier's recommendation of (b) (4) (b) (4) cycles.

b) SOP (b) (4) /PRD/004 Clean Room Entry - Exit Procedure, which is applicable to the clean room areas of (b) (4) in (b) (4) plant, which includes lines utilized in the manufacture of pharmaceuticals destined for the U.S. market, including: (b) (4) (b) (4) (b) (4) (b) (4) requires use of sterile goggles prior to entry into the clean room area. However, you have not validated the number of cleaning and sterilization cycles through which the goggles can be processed and are relying on visual inspection of the goggles by clean room operators.

c) Your Disinfectant Validation Reports dated August 2011 and November 2013 identify disinfectant / sporicidal contact times as (b) (4) for (b) (4) and (b) (4) for (b) (4). However, no contact time is specified in SOP (b) (4) PRD/006 Maintenance of Clean Room, which is applicable to the clean room areas of (b) (4) (b) (4) bag packing area and pre-sterile area in (b) (4) plant, which includes the lines utilized in the manufacture of pharmaceutical products manufactured for the U.S. market, including: (b) (4) (b) (4) (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Angela E Glenn, Investigator Anastasia M Shields, Investigator 8/26/2016 X Angela E Glenn Angela E Glenn Investigator Signed by: Angela E. Glenn -S	8/26/2016

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d) The 2016 smoke study performed in the filling area of (b) (4) line (b) (4) utilized in the manufacture of drug products including (b) (4) was inconclusive with regard to laminar air flow or the proper function of the air particle counter.

e) Revalidation Protocol (b) (4)/MFIL (b) (4) 2015 states that media fill studies on (b) (4) line (b) (4) utilized to manufacture (b) (4) for the U.S. market, are performed (b) (4).

QUALITY SYSTEM

OBSERVATION 5

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

Specifically,

a) SOP (b) (4)/PRD/041 Automatic Visual Inspection Procedure, operators performing manual visual examinations of filled drug products are trained to identify defects utilizing test kits. I observed selected examples of filled bags utilized for training operators to detect defects in (b) (4) mL (b) (4) and found one bag with a defect marked with an X and another bag with a black dot in the tub categorized as "Good".

b) According to SOP CF/CQA/023, newly hired employees with industry experience of (b) (4) or more are not required to complete on-the-job training nor are they required to perform job specific activities under supervision of a trainer.

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated

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Observation 4: Not annotated
Observation 5: Not annotated

***DATES OF INSPECTION**

8/16/2016(Tue),8/17/2016(Wed),8/18/2016(Thu),8/19/2016(Fri),8/22/2016(Mon),8/23/2016(Tue),8/24/2016(Wed),8/25/2016(Thu),8/26/2016(Fri)

8/26/2016

X Anastasia M Shields

Anastasia M Shields
Investigator
Signed by: Anastasia M. Shields -S

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EMPLOYEE(S) SIGNATURE

Angela E Glenn, Investigator
Anastasia M Shields, Investigator

8/26/2016

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