DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OS, White Oak Building 51, Room 4316 10903 New Hampshire Avenue Silver Spring, MD 20993 Phone: (301) 796-3334 ; Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	01/16/2018-01/19/2018 FEI NUMBER 3007197995

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. V.K. Shrawat, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Shilpa Medicare Limited	Deosugur Industrial Area, Deosugur
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Raichur, Karnataka, 584170, INDIA	API Manufacture

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

Equipment and utensils are not cleaned and maintained to prevent contamination that would alter the safety, identity, strength, quality or purity of the Intermediates and APIs manufactured.

THIS IS A REPEAT OBSERVATION

Specifically, on 16-17 January 2018, during the inspection of your (b) (4) which were used in the manufacturing process for (b) (4) from (b) (4) – July 2017 in Unit (b) (4) and Unit (b) (4)

Unit (b) (4) (Location of equipment used in the production of (b) (4) from (b) (4) – July 2017)

A. I observed what appears to be discoloration resembling (b) (4) inside the (b) (4) (Equipment ID: (b) (4) -25) in areas that come into direct contact with drug product. The status of this non-dedicated equipment was identified as cleaned.

Unit (b) (4) (Location of equipment proposed for use in the production of (b) (4) on or about (b) (4)

B. I observed what appears to be discoloration resembling inside the (b) (4) (Equipment ID: (b) (4) -02 & (b) (4) -12) in areas that come into direct contact with drug product. The status of this non-dedicated equipment was identified as cleaned. In addition, I observed visible signs of what appeared to be residue alongside the (b) (4) -02. Your firm did not initiate any investigations to ensure drug products manufactured in this (b) (4) was not contaminated.

C. In the (b) (4) 11, I observed the (b) (4) was torn, exposing what appears to be rust or corrosion. In addition, I noticed the gasket used to protect the (b) (4) and the (b) (4) was wrapped in

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Teflon tape. I observed missing pieces of the Teflon tape alongside the inside of the (b) (4) Your firm did not initiate any investigations to ensure the missing Teflon pieces did not contaminate drug products manufactured in this non-dedicated (b) (4)

Unit (b) (4) Block (b) (4)

D. In the (b) (4) -06 & (b) (4) -09, I observed the gaskets, wrapped in Teflon tape were beginning to unravel. In addition, I observed residue on the (b) (4) of (b) (4) -09. Your firm did not initiate any investigations to ensure drug products manufactured in these non-dedicated (b) (4) were not contaminated.

Unit (b) (4) Block (b) (4)

E. Your VP of Quality and Regulatory Affairs and I observed residue in the (b) (4) -04. The status of this non-dedicated equipment was identified as cleaned. Your firm did not initiate any investigations to ensure drug products manufactured in these non-dedicated (b) (4) were not contaminated.

OBSERVATION 2
Your firm's environmental monitoring sampling plan is not clearly defined and does not represent worst-case activities and conditions.

Specifically, sample locations taken in the (b) (4) which is used in the (b) (4) stages of (b) (4) API production for:

A. Non-viable air samples are not performed under dynamic conditions.

B. Surface samples are not representative of the most critical locations.

OBSERVATION 3
Extractable and leachable studies for the (b) (4) bags (b) (4) used in the packaging of (b) (4) have not been completed.

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Specifically, your firm packages [(b) (4)] API in [(b) (4)] bags, which are subsequently placed in a [(b) (4)] Drum. However, the USP Monograph for this product references packaging and storage should be preserve in [(b) (4)] container.

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