DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE 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 Industry Information: www.fda.gov/oc/industry	3/19/2018-3/23/2018
	FEI NUMBER 3010166890

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Unnathan Shekhar, Managing Director

FIRM NAME	STREET ADDRESS
Galaxy Surfactants Limited	Plot No. M-3, MIDC Boisar
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Tarapur, Maharashtra, 401506 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 (I) (WE) OBSERVED:

1. You failed to provide appropriate GMP and position specific training to personnel for the particular operations that each employee performs as it relates to the employee's functions. Specifically

a. The operator responsible for the receiving of raw materials was not given access to the SOP that refers to the receipt of raw materials in the warehouse. The respective document, SOP # ST002-00 (Effective date 8/19/2017), Procedure for Receiving of Materials, was not available to the operator in the warehouse.

b. Only 9 out of (b) (4) (include technical staff and the operators) employees at the firm received cGMP training in 2017. However, SOP # QA011-00 (Effective date 8/12/2017), Training and Evaluation, section 4.1.31 states training frequency (b) (4) in a (b) (4). In addition, firm also did not provide any refresher training as per section 4.1.33 of the SOP that has a provision for refresher training (b) (4) in (b) (4)

2. Your firm failed to validate the analytical methods required for the trace analysis of API residue as part of the cleaning validation program. Specifically, there is not validation report that confirms the sensitivity of <USP621> analytical method to detect the established acceptable level of the residue or contaminants. The method's attainable recovery level is also not established.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Rajiv R. Srivastava -S Digitally signed by Rajiv R. Srivastava -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002112232, cn=Rajiv R. Srivastava -S Date: 2018.03.23 09:38:45 -04'00'	Rajiv R Srivastava, Investigator	3/23/2018

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3. Your firm failed to place on stability at least one batch of manufactured APIs to monitor the stability characteristics of the API, and to test for appropriate storage conditions and confirm expiry dates. Specifically in 2016, you did not confirm the stability characteristics and storage conditions for a number of APIs including; (b) (4) Lot # (b) (4), (b) (4) Lot # (b) (4) and (b) (4) Lot # (b) (4) These APIs were manufactured in 2016 and shipped to US.

4. Your annual product review procedure is deficient such that:

a. You failed to conduct APR for your product (b) (4) for year 2016-17.

b. You did not include the stability data for 2016-17 in the APR 2016-17. The 2016-2017 APR for (b) (4) (b) (4) (Document # QA/M-3/APQR (b) (4) 16-17/00) contain only the observations (not the actual data) with respect to the product specifications (complies with specification) for the APIs that were manufactured in 2011 and 2012. Similarly, the 2016-17 APR for (b) (4) (Document # QA/M3/APQR (b) (4) 16-17/00) contains only the observations (not the actual data) with respect to the product specifications (complies with specification) for the API that was manufactured in 2011.

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	Rajiv R. Srivastava	Rajiv R Srivastava, Investigator	3/23/2018