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 Spring, MD 20993 (301) 796-3334 Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	3/26/2018 – 3/30/2018
	FEI NUMBER 3004879807

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Milind Patil, General Manager

FIRM NAME	STREET ADDRESS
Galaxy Surfactants Limited	Plot No. N46, MIDC Boisar
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Tarapur, Maharastra, 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. The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically,

a. The SOP # QC029-01 (Effective date 3/15/2018), Sampling and Testing of Water for Chemical Analysis does not include specifications for (b) (4) water that is used as raw material in the manufacturing of API, (b) (4) (b) (4)

b. You did not follow your SOP # QC003-00 (Effective date 9/1/2017), Inspection, Sampling, Testing, and Clearance of Finished Goods. You used a non USP and a non-validated method, OCN_USP to release a number of batches of (b) (4) including; Lot # (b) (4) (b) (4) These batches were released between 2/17/2018 – 3/5/2018.

c. You failed to review the process validation report such that your summary report (PVR/OCN-Retro/00) did not include a number of critical parameters including; manufacturing instructions for Stages (b) (4) – (b) (4) and also for the (b) (4) Stage where you blend several lots (obtained from (b) (4) at Stage (b) (4), identity of the various equipment used for Stages (b) (4) – (b) (4) and also for the (b) (4) stage of blending, in-process specifications, and the assay data (53 out of (b) (4) are missing from the table 18.3 on page 29.

2. Your firm failed to (adequately) validate the analytical method for stability studies of API, (b) (4) to support the intended commercialization period and expiry.

Specifically,

a. GC method, GQM 157 used for the test is neither a USP method nor an internal validated method.

b. Your firm is currently using GC method, GQM 157 for the stability testing of API, (b) (4) but you have not completed forced degradation studies with this method.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Rajiv R. Srivastava	Rajiv R Srivastava, Investigator	03/30/2018

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg 51, Rm 4225 Silver Spring, MD 20993 (301) 796-3334 Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	3/26/2018 – 3/30/2018
	FEI NUMBER 3004879807

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Milind Patil, General Manager

FIRM NAME	STREET ADDRESS
Galaxy Surfactants Limited	Plot No. N46, MIDC Boisar
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Tarapur, Maharastra, 401506, India	Manufacturer

c. You have conducted forced degradation study for (b) (4) at (b) (4) (Document no. OCN/FDS-1/01-00) and used a non-validated HPLC method as an analytical tool. However, you use a non-validated GC method, GQM 157 as the stability test method at your site N46.

3. You failed to place on stability at least one batch per year of manufactured APIs and to test at least annually to confirm the stability characteristics of the APIs, appropriate storage conditions and confirm the expiry dates. Specifically,

a. In 2016, you did not confirm the stability characteristics and storage conditions for a number of APIs including: (b) (4) Lot (b) (4) These APIs were manufactured in 2016 and shipped to US.

b. In 2017, your firm only placed (b) (4) on accelerated stability and did not place the products on long term stability studies.

4. Your firm failed to provide GMP training to your employees at the particular operations that the employee performs and GMP as it relates to the employee's functions. Specifically, Only 4 out (b) (4) employees (that includes technical staff and the operators as per your Site Master File, SMF-N46-00, Effective date 1/15/2018, page 13) received the GMP training in 2016 and no training was given in 2017. However, SOP # QA011-00 (Effective date 8/12/2017) Training and Evaluation, section 4.1.31 states training frequency should be conducted (b) (4) a (b) (4) In addition, you have not provided any refresher training as per section 4.1.33 of the SOP that has a provision for refresher training (b) (4) in (b) (4)

5. Your firm failed to establish an appropriate equipment cleaning procedure to assure an adequate cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs.

Specifically,

Your SOP # PR003-01 (Effective date 2/23/2018) does not specify the maximum time that elapse between the completion of processing and equipment cleaning, when appropriate. In addition, your procedure does not include equipment clean hold time limits prior manufacturing processes.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Rajiv R. Srivastava	Rajiv R Srivastava, Investigator	03/30/2018

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg 51, Rm 4225 Silver Spring, MD 20993 (301) 796-3334 Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	3/26/2018 – 3/30/2018
	FEI NUMBER 3004879807

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Milind Patil, General Manager

FIRM NAME	STREET ADDRESS
Galaxy Surfactants Limited	Plot No. N46, MIDC Boisar
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Tarapur, Maharastra, 401506, India	Manufacturer

6. Your firm failed to conduct appropriate qualification (DQ, IQ, OQ & PQ) of critical equipment. Specifically, you have not completed the qualification of multiple equipment including but not limited to: (b) (4) (b) (4) 9 (b) (4) 9) and (b) (4) 11 (b) (4) 11), which are used in the Stage (b) (4) to manufacture (b) (4) (b) (4) and Step (b) (4) for (b) (4) blending step to manufacture (b) (4) respectively. These non-qualified equipment were used to manufacture and ship APIs to US including; (b) (4) Lot # (b) (4)

7. Your firm failed to use water that is suitable for manufacturing of API, (b) (4) .
Specifically,
You manufacture (b) (4) water (b) (4) water) at your site from municipality water. The manufactured water quality does not meet (or exceed) with the potable water quality such that the pH of water was > (b) (4) on multiple days including; (b) (4) (pH (b) (4) , (b) (4) (pH (b) (4)), and (b) (4) (pH (b) (4) . There were no investigations to correct the water system to meet (or exceed) potable water specification.

8. You do not ensure product quality uniformity from batch to batch such that your Batch Manufacturing Records (BMR) does not conform to the Master Formula Record (MFR). You revised your BMR (BMR- (b) (4) -001-01, Effective date 11/25/2017) for Crude (b) (4) outside the MFR (MFR (b) (4) 001-00, Effective date 8/4/2017) and did not update your MFR. This BMR was used to manufacture an intermediate for multiple APIs that were shipped to US including; (b) (4) , (b) (4) , and (b) (4) .

9. Your APQR procedure is deficient such that:
a. You manufactured (b) (4) products at your site N46 but you conducted APQR for only one product, (b) (4) (b) (4) in 2016-2017.
b. The APQR for (b) (4) (APR/N46/01/04) does not contain long term stability data for 2016.
c. In your document APR/N46/01/04, you failed to acknowledge a recall and customer complaint. On page 16, you concluded that there were no recall and customer complaints.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Rajiv R. Srivastava	Rajiv R Srivastava, Investigator	03/30/2018