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	8/20/2018 - 08/24/2018
	FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Shailesh Laul, Senior Vice President, Operations

FIRM NAME	STREET ADDRESS
Strides Pharma Science Limited	36/7, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bengaluru, Karnataka, 562106, India	Drug Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
OBSERVATION 1

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used and parameters relevant to the operation.

Specifically,

A. The cleaning procedures for formulation filling equipment such used to manufacture (b) (4) Solution (b) (4) % and (b) (4) Solution USP (b) (4) mEq/(b) (4) mL do not specify the cleaning operations for the transfer pump. The transfer pump is shared for liquid products, is unidentified, and includes product contact surfaces. Cleaning records for the transfer pump are discarded, not included in batch records, and not recorded in log books.

B. After cleaning, residual clear liquid was observed in common manufacturing vessels used for production of (b) (4) Solution (b) (4) % and (b) (4) Solution USP (b) (4) mEq/(b) (4) mL.

C. Oil was observed on product contact surfaces of (b) (4) of filling equipment used for production of (b) (4) (b) (4) Solution USP (b) (4) mEq/(b) (4) mL.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Andrew J. Idzior -S Digitally signed by Andrew J Idzior -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000367360, cn=Andrew J Idzior -S Date: 2018.08.24 08:11:46 -04'00'	Andrew Idzior, Investigator	08/24/2018

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OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

The settings used to adjust the cap tightness of containers for (b) (4) Solution USP (b) (4) mEq/(b) (4) mL are not specified in work instructions or recorded in batch records. The settings to adjust the (b) (4) and height of the (b) (4) sealer used during packaging of (b) (4) Solution USP (b) (4) mEq/(b) (4) mL are not specified or recorded in batch records. The settings used to adjust the fill volume of (b) (4) (b) (4) Solution USP (b) (4) mEq/(b) (4) mL are not specified in work instructions or recorded in batch records.

OBSERVATION 3

The specifications for components, drug product containers or closures and labeling are deficient in that they do not include a description of the testing to be performed.

Specifically,

The QC test method for incoming acceptance of bottles used for packaging of (b) (4) Solution USP (b) (4) mEq/(b) (4) mL does not specify to examine the (b) (4) of the bottles.

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