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	5/22/2017-5/26/2017*
	FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Shailesh Laul, Senior Vice President - Manufacturing Operations

FIRM NAME	STREET ADDRESS
Strides Shasun Limited	KRS Gardens, Suragajakkanhalli, Indlawadi Cross, Anekal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bangalore South, Karnataka, 562106,India	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:

OBSERVATION 1

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically, your firm has received multiple complaints relating to the quality of your (b) (4) capsule products. Although your firm conducted investigations into the manufacturing process, your investigations did not arrive at the actual root cause to take the appropriate corrective actions. For example, the following complaints were related to the sticking together of your (b) (4) capsules within your firm's product bottles.

Complaint Number	Product Name	Nature of Complaint
ODF/MC/2016/106	(b) (4) Capsules USP (b) (4) mg	Capsules sticking together
ODF/MC/2015/103	(b) (4) Capsules (b) (4) mcg	Capsules were sticking / melting together

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Tamil Arasu, Investigator
Darren S. Brown, Investigator

DATE ISSUED
5/26/2017

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	5/22/2017-5/26/2017*
	FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Shailesh Laul, Senior Vice President - Manufacturing Operations

FIRM NAME	STREET ADDRESS
Strides Shasun Limited	KRS Gardens, Suragajakkanhalli, Indlawadi Cross, Anekal
CITY, STATE, ZIP CODE, COUNTRY: Bangalore South, Karnataka, 562106,India	TYPE ESTABLISHMENT INSPECTED: Drug Manufacturer

ODF/MC/2015/120	(b) (4) Capsules (b) (4) mcg	Capsules sticking / lumping
ODF/MC/2016/072	Capsules mcg	Capsules were sticking / melting together
ODF/MC/2016/077	Capsules mcg	Capsules stuck together
ODF/MC/2016/085	(b) (4) Capsules (b) (4) mg	Capsules stuck together
ODF/MC/2016/086	Capsules mg	Capsules stuck together
ODF/MC/2016/090	Capsules mg	Capsules stuck together
ODF/MC/2016/101	Capsules mg	Capsules stuck together
ODF/MC/2016/108	Capsules mg	Capsules stuck together
ODF/MC/2015/104	(b) (4) Capsules USP (b) (4) mg	Capsules were stuck together
ODF/MC/2016/045	(b) (4) Capsules USP (b) (4) mg	Capsules were stuck together

Despite receiving these quality related complaints you did not extend your investigation to evaluate if the quality measures taken during the (b) (4) step represent the entire batch.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamil Arasu, Investigator TA Darren S. Brown, Investigator DB	5/26/2017

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	5/22/2017-5/26/2017*
	FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Shailesh Laul, Senior Vice President - Manufacturing Operations

FIRM NAME	STREET ADDRESS
Strides Shasun Limited	KRS Gardens, Suragajakkanhalli, Indlawadi Cross, Anekal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bangalore South, Karnataka, 562106,India	Drug Manufacturer

OBSERVATION 2

Samples taken of in-process materials for determination of conformance to specifications are not representative.

Specifically, there is no scientific rationale or data to support the sampling plan your firm uses for testing the (b) (4) capsules in (b) (4) on (b) (4) Furthermore, your manufacturing batch record directions are inadequate in that they only specify that operators are to take samples from (b) (4) and that your operators collect only a total of (b) (4) capsules per (b) (4) for (b) (4) testing, even though each (b) (4) contains (b) (4) According to your firm's Chief Operating Officer each of the (b) (4) contains approximately (b) (4) capsules.

The following US marketed (b) (4) capsules that are (b) (4)

- (b) (4) Capsules USP (b) (4) mg
- (b) (4) Capsules (b) (4) mg
- (b) (4) Capsules (b) (4) mg
- (b) (4) Capsules USP (b) (4) mg

OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, your firm has either failed to establish (b) (4) hold times or where (b) (4) hold times have been established the batch sizes for the hold time studies do not represent those of commercial batches. Furthermore, the batch sizes are not justified for the (b) (4) hold time studies that your firm did conduct.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamil Arasu, Investigator TA Darren S. Brown, Investigator DB	5/26/2017

For example,

a) You have failed to establish (b) (4) hold times for the following commercial drug products:

- (b) (4) Tablets (b) (4) mg / (b) (4) mg / (b) (4) mg)
- (b) (4) Tablets (b) (4) mg / (b) (4) mg / (b) (4) mg / (b) (4) mg / (b) (4) mg)
- (b) (4) g / (b) (4) g / (b) (4) g / (b) (4) g)
- (b) (4) Tablets (b) (4) mg / (b) (4) mg / (b) (4) mg / (b) (4) mg / (b) (4) mg (b) (4) mg
- (b) (4) Tablets, USP (b) (4) mg / (b) (4) ng)

b) The following are examples of products intended for the US market where your firm has conducted (b) (4) hold time studies using batch sizes which do not represent commercial batches:

Drug Product Name	Commercial Batch Size of the (b) (4)	Quantity used for (b) (4) Hold Time Study
(b) (4) ablets USP (b) (4) mg)	(b) (4)	
(b) (4) Tablets, USP ((b) (4) mg)		
(b) (4) Tablets (b) (4) ng)		

*DATES OF INSPECTION
5/22/2017(Mon),5/23/2017(Tue),5/24/2017(Wed),5/25/2017(Thu),5/26/2017(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamil Arasu, Investigator Darren S. Brown, Investigator	5/26/2017