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.

<table>
<thead>
<tr>
<th>Complaint Number</th>
<th>Product Name</th>
<th>Nature of Complaint</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODF/MC/2016/106</td>
<td><a href="4">B</a> Capsules USP <a href="4">B</a> mg</td>
<td>Capsules sticking together</td>
</tr>
<tr>
<td>ODF/MC/2015/103</td>
<td><a href="4">B</a> Capsules <a href="4">B</a> mcg</td>
<td>Capsules were sticking / melting together</td>
</tr>
</tbody>
</table>

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EMPLEOS: SIGNATURE

DATE ISSUED 5/26/2017
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

TO: Mr. Shailesh Lall, Senior Vice President - Manufacturing Operations

FIRM NAME  
Strides Shasun Limited

STREET ADDRESS  
KRS Gardens, Surajajakhanhalli, Indlawa Cross, Anekal

CITY, STATE, ZIP CODE, COUNTRY  
Bangalore South, Karnataka, 562106, India

TYPE ESTABLISHMENT INSPECTED  
Drug Manufacturer

<table>
<thead>
<tr>
<th>ODF/MC</th>
<th>Capsules</th>
<th>mg</th>
<th>Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015/120</td>
<td>(b)(4)</td>
<td>Capsules sticking / lumping</td>
<td></td>
</tr>
<tr>
<td>2016/072</td>
<td>(b)(4)</td>
<td>Capsules were sticking / melting together</td>
<td></td>
</tr>
<tr>
<td>2016/077</td>
<td>(b)(4)</td>
<td>Capsules stuck together</td>
<td></td>
</tr>
<tr>
<td>2016/085</td>
<td>(b)(4)</td>
<td>Capsules stuck together</td>
<td></td>
</tr>
<tr>
<td>2016/086</td>
<td>(b)(4)</td>
<td>Capsules stuck together</td>
<td></td>
</tr>
<tr>
<td>2016/090</td>
<td>(b)(4)</td>
<td>Capsules stuck together</td>
<td></td>
</tr>
<tr>
<td>2016/101</td>
<td>(b)(4)</td>
<td>Capsules stuck together</td>
<td></td>
</tr>
<tr>
<td>2016/108</td>
<td>(b)(4)</td>
<td>Capsules stuck together</td>
<td></td>
</tr>
<tr>
<td>2015/104</td>
<td>(b)(4)</td>
<td>Capsules USP</td>
<td></td>
</tr>
<tr>
<td>2016/045</td>
<td>(b)(4)</td>
<td>Capsules were stuck together</td>
<td></td>
</tr>
</tbody>
</table>

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.

DATE OF INSPECTION  
5/22/2017-5/26/2017*

FEI NUMBER  
3004554612

SEE REVERSE OF THIS PAGE

EMPLOYEES SIGNATURE  
Tamil Arau, Investigator  
Darren S. Brown, Investigator

DATE ISSUED  
5/26/2017
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

Firm Name: Strides Shasun Limited
Street Address: KRS Gardens, Surujagakkanhalli, Indlawadi Cross, Anekal
City, State, Zip Code, Country: Bangalore South, Karnataka, 562106, India
Type Establishment Inspected: 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 [redacted] capsules in [redacted] on [redacted]. Furthermore, your manufacturing batch record directions are inadequate in that they only specify that operators are to take samples from [redacted] and that your operators collect only a total of [redacted] capsules per [redacted] for [redacted] testing, even though each [redacted] contains [redacted] capsules. According to your firm’s Chief Operating Officer each of the [redacted] contains approximately [redacted] capsules.

The following US marketed [redacted] capsules that are [redacted]

- [redacted] Capsules USP [redacted] mg
- [redacted] Capsules [redacted] mg
- [redacted] Capsules [redacted] mg
- [redacted] Capsules USP [redacted] 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 [redacted] hold times or where [redacted] 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 [redacted] hold time studies that your firm did conduct.

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DATE ISSUED
5/26/2017

FORM FDA 483 (05/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 3 OF 4 PAGES
For example,

a) You have failed to establish [redacted] hold times for the following commercial drug products:

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Commercial Batch Size of the</th>
<th>Quantity used for Hold Time Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets USP</td>
<td>(b)(4) mg</td>
<td>(b)(4) mg</td>
</tr>
<tr>
<td>Tablets USP</td>
<td>(b)(4) mg</td>
<td>(b)(4) mg</td>
</tr>
<tr>
<td>Tablets</td>
<td>(b)(4) mg</td>
<td>(b)(4) mg</td>
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</tr>
<tr>
<td>Tablets</td>
<td>(b)(4) mg</td>
<td>(b)(4) mg</td>
</tr>
<tr>
<td>Tablets</td>
<td>(b)(4) mg</td>
<td>(b)(4) mg</td>
</tr>
</tbody>
</table>

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

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