

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 6/13/2019-6/21/2019*
	FEI NUMBER 3006549835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shailesh N Patel, Vice President

FIRM NAME Dr. Reddy's Laboratories Ltd.	STREET ADDRESS P1 - P9 Q1 - Q5, Phase III, VSEZ, Duvvada
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam, Andhra Pradesh, 530046 India	TYPE ESTABLISHMENT INSPECTED 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

Acceptance criteria were not established prior to the performance of validation activities.

Specifically, is not clear how your firm determined the acceptance criteria for the (b) (4) Functionality Testing (Break loose force & Glide force) conducted as part of finished product release specification for (b) (4) Injection (b) (4) mg (b) (4) nL.

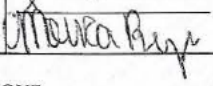
For example, your firm explained that the worst-case condition was considered for the applied injection (b) (4) based on the container size as part of the criteria to test the samples. Your data was only obtained for the (b) (4) samples from stability study for 24 months for (b) (4) (b) (4) (Batches: (b) (4) (b) (4) as reference data for Break loose force of (b) (4) Newton and Glide force of (b) (4) Newton.

However, your firm established the test limit for Break loose force as (b) (4) Newton and for Glide force as (b) (4) Newton as the finished product release specification test limits. This was not supported by scientific data that demonstrated the impact to the end user or to the finished product functionality.

OBSERVATION 2

The device design was not correctly translated into production specifications.

Specifically, your Acceptance Quality Limit [AQL] does not take into account the component critical dimensions specification during receipt of components for the manufacture of (b) (4) Injection (b) (4) ng (b) (4) nL such as (b) (4) and stoppers.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Farhana Khan, Investigator Monica C Burgos Garcia, Investigator	DATE ISSUED 6/21/2019
	<small>Farhana Khan Investigator Signed By: 1309172865 Date Signed: 06-21-2019 07:28:52</small> 	

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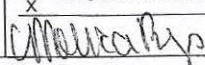
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***DATES OF INSPECTION**
6/13/2019(Thu), 6/14/2019(Fri), 6/17/2019(Mon), 6/18/2019(Tue), 6/19/2019(Wed), 6/20/2019(Thu),
6/21/2019(Fri)

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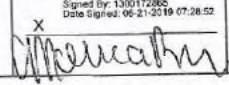
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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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