DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville MD, 20857 Industry Information: www.fda.gov/oc/industry	10/22-30/2018
	FEI NUMBER 3006549835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Vikram Shukla, Vice President - Injectable

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Ltd.	P1 - P9 Q1 - Q5 Vsez, Duvvada
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Visakhapatnam, Andhra Pradesh, 530046, India	Drug Product Manufacturer

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

PRODUCTION SYSTEM

OBSERVATION 1

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

Your Quality Unit failed to implement adequate and reliable controls for ensuring that distributed liquid injectable drug products or any of its components always comply with the quality they represent to possess.

All the following adverse incidents correspond to sterile liquid drug product lots that were sealed (b) (4) in the sealing equipment PR-007.

In January, 2018, your firm recalled one (1) lot of Docetaxel Injection USP 20 mg/ mL (USA market); Lot H7044; expiration date 05/2019, due to consumer complaints related to critical sealing defect (i.e. seal and stopper comes off the vial, making vial wide open and exposed). This critical defect was acknowledged in each of the four (4) complaints reported for the affected lot.

First complaint was received on 10/20/2017. The complainant stated that "had seven (7) vials of Docetaxel Injection USP 20 mg/ mL; Lot H7044 where the entire top comes off when trying to administer the medication and the whole vial is wide open, exposing the inside of the vial". Your Quality Unit initiated a manufacturing Investigation Report (IR) 200263810 on 10/21/2018. No Field Alert (FAR) was submitted to the agency.

IR 200263810 disclosed that all in-process controls and released testing for Lot H7044 were as expected. However, based on the complaint nature, the investigation identified (b) (4) major contributors for the confirmed critical sealing defects (b) (4)

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		JOSE E. MELENDEZ, INVESTIGATOR JUNHO PAK, INVESTIGATOR	10/30/2018

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None of the referenced sealing (b) (4) critical process parameters were validated in the sealing equipment PR-E007 by the time the referenced complaint was received.

As part of the manufacturing investigation IR 200263810, representative reserve samples of (b) (4) lots were evaluated for (b) (4) seal removal. It was identified that one (1) vial from (b) (4) lot of (b) (4) Injection (Indian market); Lot (b) (4) and (b) (4) Injection (Indian market); Lot (b) (4) showed also the critical sealing defect. As corrections, your Quality Unit proposed the implementation of manual (b) (4) functionality test during sealing activity and qualification of sealing (b) (4) critical process parameters.

Second complaint for Docetaxel Injection USP 20 mg/ mL (USA market); Lot H7044 was received on 11/08/2018. The complainant stated "the whole top of the vials is loose and when tried to pull the cap off, the whole metal part comes off (aluminum seal)". Your firm initiated the manufacturing IR 200266437 and submitted a FAR to the agency on 11/09/2018. For the period from 10/20/2017 (first complaint was received) to 11/09/2017 (second complaint was received) approximately (b) (4) vials of Docetaxel Injection USP 20 mg/ mL; Lot H7044 were distributed into USA market. After the second complaint received for Lot H7044, your Quality Unit determined to recall this lot.

In addition,

Additional complaint was received on 12/26/2017 for (b) (4) Injection USP (b) (4) mg/(b) (4) mL (USA market); Lot (b) (4) expiration date (b) (4) The complainant reported two (2) observations:

* vial 1- liquid leak found between the (b) (4) cap and the vial
* vial 2 – (b) (4) seal came off from the vial where the (b) (4) cap remains on the seal

Manufacturing IR 200273645 was initiated and a FAR was submitted to the agency on 12/28/2017. The IR 200273645 disclosed no discrepancy during the manufacturing process of Lot (b) (4). All the in-process controls and released testing for Lot (b) (4) were as expected. As part of the investigation, the reserve samples of Lot (b) (4) were also inspected, and no loose seal or leakage was observed. Your Quality Unit concluded that if seal on its place, the vial is integral. No additional actions were considered.

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As corrections, your Quality Unit defined (b) (4) for removal of (b) (4) in alignment with the supplier specification (06/2018); implemented (b) (4) functionality test(02/2018), and carried out validation activities of the sealing (b) (4) critical process parameters for (b) (4) vials (12/2017) .

The lack of qualifying the sealing critical parameters such as, (b) (4) (b) (4) do not ensure that each sterile liquid drug products lot (b) (4) in (b) (4) equipment PR-E007 prior to December 2017, is impacted by the defect of seal and (b) (4) stopper comes off.

Repeat Observation from WL 320-16-02 & FDA-483 March 2017.

LABORATORY CONTROL SYSTEM

OBSERVATION 2

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product that may have been associated with the specific failure or discrepancy.

Specifically, investigations into confirmed Out of Specification (OOS) results and identified manufacturing equipment defects were not included and considered for batch disposition of previously manufactured products, on the affected manufacturing equipment. The Quality Unit did not expand the sampling and testing program on the affected batches observed with low or OOT assay results, manufactured with known equipment defect.

(b) (4) Tablet, (b) (4) mg, batch# (b) (4) was rejected due to a confirmed OOS (A.V.= (b) (4) , exceeding the A.V. value of (b) (4) for (b) (4) requirements for Uniformity of Dose (UOD). This batch also yield low assay results (b) (4) .

The OOS investigation 310016050 was initiated on 31Aug18, identified a defect on the (b) (4) seal to the (b) (4) machine (b) (4) (PR-E648), resulting in poor (b) (4) operations on the (b) (4) The seal leak resulted in the process control (HMI) to run the (b) (4) to near to maintain the (b) (4) (b) (4) deviating from the typical (b) (4) The OOS investigation identified low assay values on previously manufactured batches of (b) (4) Tablets, manufactured on the same defective (b) (4) Machine (b) (4) (PR-E648). (b) (4) Tablet batch numbers (b) (4) expiration date (b) (4)

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(b) (4) (b) (4) expiration date (b) (4) and (b) (4) expiration date (b) (4) reported lower assay results of (b) (4) respectively (assay specification limit = (b) (4) %).

During the manufacturing of the (b) (4) previously (b) (4) Tablet batches (b) (4) (b) (4) the (b) (4) were operating near the (b) (4) indicating the same equipment defect. No additional tests were performed to justify the release of the impacted batches, manufactured on the equipment with known equipment defect. All (b) (4) impacted batches of (b) (4) Tablets were released for distribution to USA market.

Repeat Observation from WL 320-16-02 & FDA-483 March 2017.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed.

Your control procedures SOP FTDQA007-02; dated on 02/28/2018 "Aseptic Process Simulation (Media Fill)" and SOP FT07-QA-0022; dated on 07/31/2018; version 2.0 "Handling of Interventions during routine production activity" were found inadequate. Specifically, these control procedures do not require a periodic simulation of new and highly critical intervention (corrective intervention) observed during routine commercial process.

A. For example, Incident Report (IR) 200241685 was initiated on 05/29/2017, due to a new corrective intervention i.e. (b) (4) The intervention was performed on 05/27/2017 by two (2) operators in (b) (4) PR-E007 filling Line (b) (b) (4) (4) operation of (b) (4) drug product (b) (4) Injection (b) (4) mg/vial; Lot (b) (4) ; expiration date (b) (4) (b) (4) (b) (4) fill volume adjustment and filling operation were completed. The IR 200241685 identified a damage in the (b) (4) as the root cause for this new corrective intervention.

Same corrective intervention was also carried out on 07/04/2017, in (b) (4) PR-E007 filling Line (b)(b) (4) (4) (b) (4) operation of (b) (4) drug product (b) (4) Injection (b) (4) mg/vial; Lot (b) (4) expiration date (b) (4) However, no incident report was initiated to assess the impact of (b) (4) intervention over the

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aseptic filling operations for Lot (b) (4). Moreover, no root cause was identified to prevent reoccurrence of having a mechanical intervention in the (b) (4) while processing.

(b) (4) corrective intervention was simulated during set-up process of (b) (4) PR-E007 filling Line (b) (4) in two (2) successive media fill Lots (b) (4) (dated on 05/31/2017) and (b) (4) (dated on 06/07/2017). However, your firm simulated the intervention during the set-up process of the filling Line (b) (4) instead of simulating it during aseptic filling process, which is where the worst condition is represented. Moreover, there is no evidence in the media fill batch records (Lots (b) (4) and (b) (4)), which demonstrate the corrective intervention was performed by two (2) operators.

Your Quality Unit failed to include (b) (4) intervention in the list of the corrective and highly critical interventions that should be periodically simulated as part of your media fill program.

Your firm has carried out approximately nine (9) media fill runs (b) (4) (b) (4) in aseptic filling Line (b) (4) since the corrective action was observed on 07/04/2017.

Repeat Observation from WL 320-16-02.

B. There is no assurance that your process simulation studies (media fills) performed in the (b) (4) PR-E007 filling Lines (b) (4) are truly representative of the conditions observed and/or that might occur during routine aseptic filling operations of vials.

This is evidenced in that, although corrective and inherent operator's interventions are simulated during the media fills, the duration at which these interventions are simulated is not established based on an historical and/or retrospective evaluation.

Your current practice does not ensure the extension of each of the interventions is accurately simulated during the aseptic-process (media fill) runs.

C. The control procedure SOP FT7QC247; dated on 05/29/2018; "Microbiological Viable Monitoring Program"

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establishes the following rationale for selecting the sample sites for microbiological monitoring into the ISO 5 area of (b) (4) PR-E007:

* Sites where activities that contribute spread of contamination
* Sites, which if contaminated, have adverse effect on product quality

Per control procedure SOP FT7QC247, (b) (4) located in ISO 5 area of (b) (4) PR-E007 was selected for surface sampling monitoring. This location was selected to ensure aseptic conditions of the filling (b) (4)

The control procedure SOP FT7QC247 was found inadequate, in that not requires that surface sampling monitoring must (swab sampling method) must be collected from the (b) (4) that was in use during the aseptic filling process.

For example, on 10/29/2018, I witnessed the aseptic filling process of (b) (4) Injection (b) (4) mg/vial; Lot (b) (4) . This lot was aseptically filled using the (b) (4) ocated into (b) (4) PR-E007. However, the surface swab sampling collected by the (b) (4) the filling process was carried out in (b) (4) which does not truly represent the worst surface sample site for filling process of Lot (b) (4)

D. Specifically, inadequate collection filters were used to confirm the retention of (b) (4) during the (b) (4) filter validations. The microorganism retention study was conducted to verify absolute retention of the test organisms on the (b) (4) um (b) (4) product filters. The collection filter with pore size of (b) (4) um are placed (b) (4) to the (b) (4) filters and used to validate the absolute retention of the test microorganism, (b) (4) . Due to the (b) (4) pore size of the collection filters, (b) (4) that may have penetrated the (b) (4) um (b) (4) filters may not be detected by the (b) (4) um collection filters, resulting in false negative result. The (b) (4) um collection filters were used during the (b) (4) filter validation studies for products intended for U.S. market, including (b) (4) njection and (b) (4) injection.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions

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The control procedure SOP FTDQA004-00; dated on 09/14/2017; "Air flow Visualization for Clean Rooms/ Zones" establishes/requires:

* Section 6.3.18.1 – The study is to evaluate the impact of all the production interventions performed by human, machine during routine operation on air flow pattern demonstrated at operation.

* Section 6.3.18.20 – Interventions: all the aseptic manipulations and interventions shall be captured during the dynamic smoke study i.e. inherent interventions that occur during operational conditions and corrective interventions that may occur when machinery is not operating.
Nonetheless, your air flow pattern study conducted during filling equipment assembly and process for (b) (4) PR-E007, and documented in the DVD; Doc. FT7APRPQP235-11(A) "Air Flow Visualization Study; Vial Line (b) (4) Block (b) (4) njection" dated 01/11/2017, utilized to ensure unidirectional airflow during manufacture of aseptically filled drug products, is deficient in that do not demonstrate how the air flow pattern of the ISO-5 area of the (b) (4) PR-E007 vial filling Line (b) (4) is affected by a new corrective intervention (b) (4) position from (b) (4) to (b) (4) or vice versa".

Per media fill run DVD; Lot (b) (4) (dated on 05/31/2017), the corrective intervention was performed by two (2) operators. One of the operator was in the (b) (4) of the filling Line (b) (4) and the other operator was in the (b) (4) (b) (4) of the filling Line (b) (4) Both operators simultaneously carried out the intervention in the ISO-5 area of the (b) (4) PR-E007 vial filling Line (b)

Repeat Observation from FDA-483 March 2017.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed

Specifically, your Quality Unit failed to conduct a comprehensive evaluation and implement appropriate and effective corrective and preventive actions to prevent reoccurrence of aborted HPLC sequence events.

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During the period between 01Jan 2018 to 15Oct 2018, there were approximately 175 events identified as "repeated incidences" from QC, including at least 19 events due to column conditioning and 15 poor column performances that resulted in aborted or invalid HPLC sequence runs. Based on your assessment and identified root causes, insufficient actions were taken by the Quality unit to ensure the robustness and suitability of the analytical test procedures and the equipment. Incident events with similar root causes were not thoroughly reviewed for historical trends and corrective actions were not implemented to reduce the occurrences of atypical events from similar root causes.

Repeat Observation from WL 320-16-02 & FDA-483 March 2017.

QUALITY SYSTEM

OBSERVATION 6

Employees engaged in the manufacture and processing of drug product lack the training and experience to perform their assigned functions.

Specifically,

A. The firm's training program does not provide comprehensive trainings to conduct the assigned job responsibilities. The trainings programs do not define the requirements for the on-the-job trainings or the qualifications for technical procedures, including operation/calibration of dissolution apparatus, GC, pH meter, Karl Fisher, etc. The self-conducted, SOP trainings are required for most operations and there are no training assessments conducted to verify the training effectiveness. Firm's personnel showed insufficient knowledge of the written procedures on the routine operations for the assigned job, resulting in numerous incidences of atypical events.

B. There are insufficient trainings provided for observed procedural or practical deficiencies, identified from atypical incident events. Refresher trainings are not always required or provided to all affected personnel, for the root causes identified in the reoccurring atypical events. Repeated atypical events from similar root causes have resulted in numerous aborted HPLC sequence runs. During Jan-Oct 2018, I've identified at least 34 repeated

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	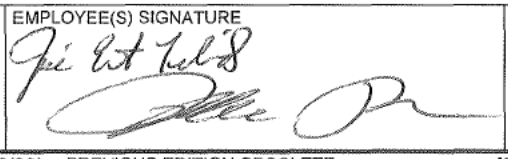	JOSE E. MELENDEZ, INVESTIGATOR JUNHO PAK, INVESTIGATOR	10/30/2018

atypical events, related to insufficient handling of HPLC columns, 19 aborted sequence runs from improper column conditioning and 15 events from poor column performance.

OBSERVATION 7

The batch production and control records are deficient in that they do not include identification of persons performing each significant step in the operation.

Specifically,

Per media fill run DVD; Lot (b) (4) (dated on 05/31/2017), the corrective intervention i.e. (b) (4) (b) (4) is carried out by two (2) operators. One of the operator is in the (b) (4) of the (b) (4) PR-E007 filling Line (b) (4) and the other operator is in the (b) (4) of the (b) (4) Both operators simultaneously carried out the intervention in the ISO-5 area of the (b) (4) PR-E007. However, the media fill batch records for Lots (b) (4) and (b) (4) and the commercial batch records for aseptic (b) (4) process of (b) (4) Injection (b) (4) mg/vial; Lots (b) (4) and (b) (4) aseptically filled in (b) (4) PR-E007 filling Line (b) (4) only document the name of one (1) manufacturing operator when the (b) (4) corrective intervention was performed.

OBSERVATION 8

An (b) (4) Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

On 10/20/2017, your Quality Unit received one (1) customer complaint related to a critical sealing defect (i.e. (b) (4) (b) (4) observed in seven (7) vials of Docetaxel Injection USP 20 mg/ mL (USA market); Lot H7044; expiration date 05/2019. Manufacturing Investigation Report (IR) 200263810 was initiated and identified (b) (4) major contributors for the confirmed critical sealing defects (b) (4) (b) (4) Investigation IR 200263810 also disclosed that none of the referenced sealing (b) (4) critical process parameters were validated in the (b) (4) PR-E007 filling Line (b) (4) (sealing equipment) by the date (10/20/2017) the complaint for Lot H7044 was received. (b) (4) PR-E007 was used during the sealing (b) (4) process of Lot H7044.

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Your Quality Unit did not submit a FAR to the agency until they received on 11/09/2017, a second complaint reporting the same critical sealing defect in lot H7044.

For the period from 10/20/2017 (first complaint was received) to 11/09/2017 (second complaint was received) approximately (b) (4) vials of Docetaxel Injection USP 20 mg/ mL; Lot H7044 were distributed into USA market. Lot H7044 was recalled.

J.E.M. 10/30/2018

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