DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov	DATE(S) OF INSPECTION 03/02/2021-03/12/2021 FEI NUMBER 3006895982
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Boddeti Varaha Rama Krishna Satya Srinivas Rao,VP & Site Head	
FIRM NAME Jubilant Generics Ltd.	STREET ADDRESS Dehradun Highway, Bhagwanpur, Roorkee
CITY, STATE, ZIP CODE, COUNTRY Hardiwar, Uttarakhand, India 247661	TYPE ESTABLISHMENT INSPECTED 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

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A- On March 2nd, 2021, non-dedicated (b) (4) equipment PR/(b) (4)/002 was observed to contain residue in the (b) (4) on the back of the (b) (4). The equipment was identified as cleaned for product change over. Since January 2019, the (b) (4) equipment has been used to manufacture the following products:

Drug Name	Indicated Use
(b) (4) (b) (4)	(b) (4)
(b) (4) (b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)

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RKakabaso	Dipesh Shah, CSO Rita K Kabaso, CSO	03/12/2021

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(b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)

(b) (4) mg USP tablets has been manufactured on this equipment and distributed to the US Market. Your current product change over cleaning for (b) (4) equipment PR/(b) (4) /002 fails to prevent potential product contamination.

B- On March 2nd, 2021, non-dedicated (b) (4) compression machine PR/TCP/011 was observed to contain (b) (4) residue (powder) on the (b) (4) after product change over cleaning. Since January 2019, the compression machine has been used to compress the following products:

Drug Name	Indicated Use
(b) (4) tablet (b) (4) mg and (b) (4) mg	(b) (4)
(b) (4) tablet (b) (4) mg and (b) (4) mg	(b) (4)
(b) (4) tablets (b) (4) mg and (b) (4) G	(b) (4)

Compressed tablet batches of products listed in the table above have been distributed to the US Market. Your current product change over cleaning for (b) (4) compression machine PR/TCP/011 fails to prevent potential product contamination.

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C- On March 2nd, 2021, non-dedicated (b) (4) machine PR/(b) (4) /001 was observed to contain (b) (4) residue on the (b) (4) wall of the (b) (4) chamber and additionally, particles, were found in the drain pike of (b) (4) chamber. Since January 2019, the (b) (4) (b) (4) machine has been used to (b) (4) the following products:

Drug Name	Indicated Use
(b) (4) tablets (b) (4) mg and (b) G	(b) (4)
(b) (4) mg and (b) (4) mg	(b) (4)

Batches of products listed in the table above have been distributed to the US Market. Your current product change over cleaning for (b) (4) machine PR/(b) (4) /001 fails to prevent potential product contamination.

D- On March 2nd, 2021, non-dedicated (b) (4) machine PR/(b) (4) /004 was observed to contain rust like surface in the (b) (4) port of the equipment and a brownish color which appeared to look like rust in the (b) (4) area. Since January 2019, the (b) (4) machine has been used to (b) (4) the following products:

Drug Name	Indicated Use
(b) (4) tablets (b) (4) mg and (b) G	(b) (4)
(b) (4) tablet (b) (4) mg and (b) (4) for all strength (b) (4) mg)	(b) (4)
(b) (4) capsules (b) (4) mg	(b) (4)
(b) (4) mg	(b) (4)

Batches of products listed in the table above have been distributed to the US Market. Your current product change over cleaning for (b) (4) machine PR/(b) (4) /004 fails to prevent potential product contamination.

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E- On March 2nd, 2021, non-dedicated (b) (4) machine DL/(b) (4) /001 was observed to have (b) (4) and blackish stains in the gasket of the (b) (4) area. Since January 2019, the (b) (4) machine has been used to process the following products:

Drug Name	Indicated Use
(b) (4) tablet (b) (4) (b) (4) mg	(b) (4)
(b) (4) tablets (b) (4) mg	(b) (4)
(b) (4) tablets (b) (4) mg and (b) (4) mg	(b) (4)

Batches of products listed in the table above have been distributed to the US Market. Your current product change over cleaning for (b) (4) machine DL(b) (4) /001 fails to prevent potential product contamination.

F- Your "Receipt, Inspection, Cleaning, Usage, Polishing and Disposal of Punches and Dies" (PR020-11) procedure, fails to ensure that manufacturing equipment is suitably maintained for its intended purpose. Your maximum tablet limit per punch and die set, is (b) (4). You failed to provide a sound justification for establishing your maximum punch and die limit. Section 6.3.2.2 of your procedure (PR020-11) indicates that each set of punches and dies procured for production will be destroyed based on a cumulative tablet count. Tablet tracking for each punch set is not performed. You utilize a (b) (4) process for all punches at the facility. For example, (b) (4) tablets (b) (4) mg which are compressed on a (b) (4) compression machine. You procured (b) (4) punch sets which include upper punch, lower punch and die (per set). During (b) (4) compression of the first set of (b) (4) tablets (b) (4) mg, the following punch (b) (4) was utilized:

Batches	Punch Set
First batch	(b) (4)
Second batch	(b) (4)

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Third batch	(b) (4)

Your current process fails to account for wear of frequently used punches. On March 8th, 2021, the following lower punches were observed to contain edge-wear, (b) (4) and (b) (4). You failed to provide a scientific justification detailing that the defects observed do not affect the identity, strength, quality or purity of your drug product.

In addition, you failed to provide a sound justification for re-inspecting the punches and dies at the intervals described in Section 6.3.2.2 of your procedure (PR020-11). For example, a set of (b) (4) punches is inspected at the following intervals

First Inspection	Second Inspection	Third Inspection	Fourth Inspection	Fifth Inspection (punch destruction)
Initial receipt	(b) (4)	(b) (4)	(b) (4)	(b) (4)

Furthermore, your dies are not stored per your manufacture's recommendation.

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OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate, sampling plans designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality and purity.

*****REPEAT OBSERVATION*****

Specifically,

A- Your "Management of cleaning validation/verification" "Document number: QA083" procedure does not represent all hard to clean locations. Your facility manufactures a total of (b) (4) different drug products. Critical manufacturing equipment such as (b) (4), (b) (4) Equipment, and compression machines are non-dedicated. Examples of hard to clean surfaces not sampled during cleaning validation include, but not limited to:

- (b) (4): inner surface of the (b) (4), groove between (b) (4) and (b) (4), groove between (b) (4) and surface (b) area, inside the discharge chute, and groove of the surface (b) (4). Brownish spots which appeared to be rust was observed in the groove between (b) (4) and (b) (4) for equipment PR/(b) (4) /001.
- (b) (4) Equipment: (b) (4) of the (b) (4) and (b) (4) bowl are not sampled.

The non-dedicated equipment at the facility is used to manufacture the following (b) (4) molecules: (b) (4). Per your Quality Assurance Manager, "cleaning validation is done for ensuring cleaning procedure efficiency to remove residue from the equipment of previous product". Your current swab sampling location do not represent all hard to clean surfaces. Your current cleaning validation fails to scientifically

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B- "Dirty hold-time" swab samples obtained from non-dedicated equipment do not represent hard to clean surfaces. Dirty hold-time study was not conducted during cleaning validation performed in December 2020, "Document number: QA083". Per your Quality Assurance Manager, during cleaning validation conducted in December 2020, product change over cleaning (Type B) was performed immediately after manufacturing. At present, you utilize dirty hold-time established prior to October 2019. Current dirty hold-time study being utilized is not robust to determine removal of previous product with prolonged dirty hold-time storage. The current dirty hold time study being used does not represent the additional hard to clean surfaces noted in "Management of cleaning validation/verification" "Document number: QA083. For example, the dirty hold-time being used for (b) (4) was approved on March 31st, 2018 under report "CVR/DEHT/001/18/00". During execution of the (b) (4) hold-time study, swab samples were not collected from the following hard to clean surfaces: (b) (4), bottom surface of (b) (4), and surface of the (b) (4). You currently have no plan on re-executing dirty hold-time and provided no sound justification for utilizing dirty-hold time conducted in March 2018.
Additionally, your firm only conducted dirty hold time studies for Compression machine, (b) (4) equipment. The rest of the equipment such as the (b) (4) and other manufacturing equipment did not have hold times studies.

C- Your firm provided no justification for using second/third worst case product to conduct extensive swab sampling. This was a part of your firm's enhance cleaning validation program by selecting "hard to clean" surfaces which is stated on page 4 of document titled, 'Cleaning Validation Protocol for Manufacturing and Packing Equipment with Extensive Swab Sampling' (dated December 31, 2019). Page 14 – 17 documents: Equipment Name,

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Validation Protocol for Manufacturing and Packing Equipment with Extensive Swab Sampling' (dated December 31, 2019). Page 14 – 17 documents: Equipment Name, Equipment ID Number and Worst-Case Product. However, upon reviewing the Worst-Case Products used no scientifically documented explanation as to why in some cases number three hard to clean product was used instead of number one or number two hard to clean product is used. For example,

1- (b) (4) -250 the firm used (b) (4) tablets which is not listed as a worst to clean product
2- Compression Machine (b) (4) the firm used (b) (4) tablets which has the third worst to clean product.
3- (b) (4) ((b) (4) L) the firm used (b) (4) tablets which has the third worst to clean product.
4- (b) (4) the firm used (b) (4) tablets which is the forth worst to clean product
5- Tablet Capsule (b) (4) the firm used (b) (4) which is not listed as a worst to clean product

D- Your cleaning validation only evaluated large volume equipment and did not evaluate smaller volume equipment. In section 6.2.5.2 of Standard Operating Procedure (SOP), QA083 document titled, 'Management of Cleaning Validation / Verification' which states, "The equipment with larger surface area (bearing larger product contact surface area) shall be considered for worst case representation and during calculation of total equipment surface area" For example your firm has the following:

1- (b) (4) L, however only (b) (4) L was evaluated (CVR/MI/MPES/001/20/06)
2- (b) (4) L, however only (b) (4) L was evaluated (CVR/SP3/002/20/00)

3- Compression Machine (b) (4), however (b) (4) (CVR/ZE1/001/19/00) and (b) (4) (CVR/SP3/001/17/00) machines were evaluated

OBSERVATION 3

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

Specifically, you failed to extend your manufacturing investigation PR58614 to other products manufactured which utilized Acceptance Quality Limit (AQL) for tablet visual inspection. Prior to December 2019, 100% manual visual inspection was not performed for all batches manufactured. You utilized, AQL analysis for batch release to ensure that your manufacturing process contained no critical defects. You define critical defects as defect "with high probability of adversely impacting the safety, purity and effectiveness of the drug product." On November 21st, 2019, you decided to initiate a voluntary recall to withdraw Amantadine Hydrochloride tablets 100mg from the US market. The recall was initiated due to a complaint regarding one compressed tablet containing a foreign particle; which was later identified as "(b) (4) particle". You failed to extend your investigation to the other (b) batches of drug product which utilized AQL inspection analysis. The (b) batches are within expiry and are currently on the US market. Adequate impact assessment of batches manufactured using AQL analysis was not performed. You failed to assure that the (b) batches which utilized AQL evaluation are free of critical defects that would affect the safety, purity and effectiveness of your product.

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OBSERVATION 4

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.

*****REPEAT OBSERVATION*****

Specifically,

A- You failed to appropriately qualify your 100% automated tablet inspection equipment. Your production block is equipped with (b) (4) automated visual inspection machines, (b) (4) . Since December 2019, all (b) (4) US products undergo 100% automated visual inspection. Your current visual inspection process fails to assure that non-conforming tablets and capsules are rejected. During equipment qualification, the following inadequacies were observed:

- Automated visual inspection machine PR/TIM/002 and PR/TIM/003 were executed using PQ/PRTIM002 and PQ/PRTIM003. Each machine is equipped with (b) (4) cameras which detect different defects. During individual camera challenge, you failed to adequately qualify Line (b) (4) /camera (b) (4) , and Line (b) (4) /camera (b) (4) to detect different tablet shapes manufactured at your facility. PR/TIM/002 and PR/TIM/003 were only challenged to detect (b) (4) shaped tablets. Tablet shapes manufactured in your facility include: (b) (4) . During individual camera challenge for (b) (4) Camera (b) (4) and (b) (4) Camera (b) (4) , you failed to ensure that the (b) (4) shape tablets used for thickness challenge are within the high and low thickness range routinely observed during production. Tablet thickness range used during qualification is unknown. In addition, the number of tablets which contained low thickness or high thickness is unknown.

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Batch simulation challenge for both (b) (4) and (b) (4) tablets was conducted by selecting (b) (4) "good tablets". You failed to provide sound justification demonstrating that the (b) (4) tablets actually contained "good tablets". A total of 13 different defects were selected for batch challenge. For each defect, (b) (4) defect tablets were generated. You failed to provide statistical analysis demonstrating that the qualification process selected is representative of batch size and number of rejects noted within a batch. After visual inspection, you failed to inspect your rejected and approved tablets to ensure that defects were appropriately rejected from the batch.

- Automated visual inspection machine PR/TIM/001 was executed using protocol RQP/PRTIM001/17/00. During qualification, you failed to qualify your automated visual inspection machine to detect tablets that contain (b) (4). In addition, during tablet thickness challenge, you failed to determine batch specific high and low thickness range routinely observed during production. Additionally, the number of tablets challenged containing low or high thickness is unknown.

Since December 2019, you have recorded 116 Out of Trend and Out of Specification results relating to assay. Eight of the 116 OOS and OOT batches underwent automated visual inspection. In addition, seven lack of efficiency complaints have been recorded at your facility since December 2019. Your current qualification fails to confidently assure that your camera can adequately reject non-conforming tablets.

B- Your firm process verification (page 14 of PVEP/SP1/001/19/00, dated February 28, 2020) and validation (page 43 of PVQP/SP1/001/20/00, dated June 10, 2020) of (b) (4) Tablets are validated with a compression speed acceptance of (b) (4). In reviewing the manufacturing parameters for tablet compression machine (PR/TCP/005) and Master Batch Record, the machine has speed is set as follows:

1- (b) (4) mg tablets: (b) (4)
2- (b) (4) mg tablets:
3- (b) (4) mg tablets:

The upper and lower speed limits were not validated.

OBSERVATION 5

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, appropriate controls are not exercised over computerized systems or data generated by computerized systems. For example,

A- You failed to ensure that your computerized systems in production were adequately backed-up. You have (b) (4) non-dedicated compression machine, (b) (4) . Electronic data generated on Programmable Logic Control (PLC) PR/TCP/010 has never been backed-up. The storage capacity of the PLC is unknown. You failed to provide a valid rationale why the data on PR/TCP/010 is not preserved. In addition, quality assurance does not review the electronic data generated on PR/TCP/010. Per your Associate Director Quality Assurance, batch production details are printed at the end of every run. The printed data undergoes quality review. The firm failed to provide a valid rationale why the true data generated is not reviewed. A total of (b) (4) batches intended for the US market which are within expiry were compressed using PR/TCP/010.

Per your "Data Backup & Retrieval of Common Network Servers, IPC, PLC & HMI" procedure, equipment located in production is backed up (b) (4) . You failed to provide a sound justification for the backup frequency selected.

B- Appropriate controls are not placed on your Programmable Logic Control (PLC) to ensure that only validated recipe parameters are entered on your (b) (4) PR(b) (4) /005. On March 2nd, 2021, PLC PR/(b) (4) /005 was observed to contain(b) (4) recipes for (b) (4) (b) (4) mg.

Recipe Number	Recipe Name	Last used	No. of cycles
(b) (4)			

You failed to provide a rational justification why (b) recipes existed for (b) (4) tablets (b) (4) mg USP. In addition, recipe parameters in PR/(b) (4) /005 can be changed by your production operators.

C- True data generated during continuous temperature monitoring of data loggers used in control/reserve room is not preserved. Per your Quality Assurance Senior Executive, continuous monitoring of hot and cold spots is conducted using single use data loggers. Your

"Management of Control, Retention and Custom Sample", "QA034-20" indicates the data loggers are replaced (b) (4) . Data from the data loggers is downloaded and then printed. During download of data, the data can be downloaded to pdf or excel. The data extracted from the data logger onto a computer prior to printing is not saved. After printing, the data loggers and the exported data is not preserved.

OBSERVATION 6

Backup data is not assured as exact, complete, and secure from alteration, erasure or loss through keeping hard copy or alternate systems.

Specifically,

A. Your firm's Information Technology Department uses a pen drive to backup manufacturing equipment data such as (b) (4) and other manufacturing equipment. The data collected from manufacturing equipment on to the drives is not assessed by Quality Department for the authenticity and the completeness of the data transfer. That data is then transferred to site back up servers. That transfer of data is also not assessed by Quality Department for the authenticity and the completeness of the data transfer. Upon reviewing your site server and corporate server backup data for January 2019 - February 2020, we found inconsistencies in files that were backed up. The folders ranged from 13 per month to 47 per month. According to IPC & HMI details of Manufacturing document the firm has (b) (4) machines being backup (b) (4) .

In addition, the pen drive used to backup manufacturing data is not secured.

B. The Human Machine Interface's (HMI) data used for controlling manufacturing equipment are not backed up and the data is not stored some examples are:
   1- Automatic Capsule Filling with equipment # PR/ACF/002
   2- (b) (4) with equipment # DL/(b) (4)/001 & PR/(b) (4)/003
   3- (b) (4) with equipment # PR/(b) (4)/003, PR/(b) (4)/001 & PR/(b) (4)/002
   4- (b) (4) with equipment # DL/(b) (4)/001, PR/(b) (4)/002, PR/(b) (4)/003 & PR/(b) (4)/001
   5- (b) (4) Machine with equipment # PR/(b) (4)/002

C- In reviewing administrative rights for you manufacturing equipment it was found that Production Department have the "Admin Responsibilities" to some of the equipment such as
   1- Table Compression Machine with equipment # PR/TCP/010
   2- Automatic Capsule Filling with equipment # PR/ACF/002
   3- (b) (4) with equipment # PR/(b) (4)/001 & PR/(b) (4)/002
   4- (b) (4) with equipment # PR/(b) (4)/001
   5- (b) (4) Machine with equipment # PR/(b) (4)/002

OBSERVATION 7

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically, your quality control unit fails to fully investigate errors that have occurred in order to support root causes identified. For example:

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PR70322 regarding (b) (4) tablets USP (b) (4) mg, lot (b) (4), Exp: Dec 2021 containing a pen cap inside the bottle. Per your conclusion, "insertion of cap of pen into bottles is not possible at manufacturing site, existing controls are available at site to detect and reject the cap of pen in bottle". You failed to appropriately assess your packaging line to ensure there are no gaps in your (b) (4) where the bottles travel prior to filling. On March 5th, 2021, a 9.5cm gap was observed on the conveyor belt. The gap was observed before the (b) (4). This is the area where the open bottle travel prior to filling. Furthermore, your investigation indicates that all employees use company provided pens which do not contain caps. However, you failed to provide justification demonstrating that prior to complaint, adequate controls were in place to limit introduction of unapproved pens in your facility.

Alarm reports generated after packaging of specific drug products on your (b) (4) line are not printed or reviewed after packaging operations.

Dates of Inspection:
March 2, 2021; March 3, 2021; March 4, 2021; March 5, 2021; March 8, 2021; March 9, 2021; March 10, 2021; March 11, 2021; March 12, 2021

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