DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/20/2022-8/1/2022*
	FEI NUMBER 3006895982

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Pramod Yadav, CEO - Pharma

FIRM NAME	STREET ADDRESS
Jubilant Generics Limited	Roorkee - Dehradun Highway
CITY, STATE, ZIP CODE, COUNTRY Sikanderpur Bhainswal, Uttaranchal, 247661 India	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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

1. OOS 125532: On 7/28/2021, your Quality Assurance Manager reviewed PR#125532 that was initiated to probe an OOS result for (b) (4) for (b) (4) mg (**Table 1**, (b) (4) and (b) (4) mg (**Table 1**, (b) (4) . According to your investigation report, OOS-INV-LI (b) (4) 0018, on 9/28/2021 your contracted lab analyzed (b) (4) batches of (b) (4) USP (b) (4) mg for (b) (4) including: Batch No's: (b) (4) (b) (4) Out of these (b) (4) batches, the OOS results were recorded for (b) (4) batches at your contracted lab's. Specification limit: NMT (b) (4) % w/w. OOS results recorded: Batch (b) (4) The investigation was performed at your contracted lab and no root cause was identified in (b) (4) (b) (4) The investigation report stated that the test was not carried out in an environ relative humidity was maintained below (b) (4) %RH and based on this the contracted lab retested new sample and invalidated the result. Your test procedure, (b) (4) (Effective date 1/6/2022) (b) (4) USP (b) (4) mg do not mention running the (b) (4) test under humidity NMT (b) (4) %RH. In addition, revi mperature and humidity record confirmed that the contracted lab only maintained the temperature (20 - 25 °C) of the lab and did not record/maintain the lab humidity. Your SOP No. QC059 R13 (Effective date 4/30/2022) Temperature

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Monitoring in Quality Control Department confirmed that only temperature is maintained for the quality control lab (NMT (b) (4) °C). There is no assurance that the (b) (4) recorded for (b) (4) (Batch No's: (b) (4) manufactured at the Jubilant represents the true values.

The respective CAPA PR#131905 stated to revise the testing procedure, STP (b) (4) by incorporating a note, "Avoid prolonged exposure of sample in the environment". It is not sure how this would have changed the outcome of the (b) (4) test results when the test procedure did not have any provision for ensuring the humidity.

Table 1. List of (b) (4) atches failing for (b) (4) and shipped to U.S.

Entry	Product Name (b) (4)	Batch No.	Number of Tablets	Mfg. Date	Expiry Date	Dispatch Date
(b) (4)						

2. On 11/10/2020, you aborted an analysis for improper peak shape and recorded Analytical Interruption Report No. AIR/20/0696. The improper peak was observed during the dissolution test of (b) (4) (b) (4) USP (b) (4) mg Batch No's: (b) (4) Your investigation reported poor column as the root cause for the improper peak. Based on this, you retested new samples on a different column and invalidated the initial result. However, review of the aborted sample set, (b) (4) revealed that the peak shape for the (b) (4) met the system suitability criteria suggesting that improper peak shape observed during the initial dissolution test was not due to column. Review of the retest analysis of sample sets, (b) (4) (for Batch No. (b) (4)) and (b) (4) (Batch No's: (b) (4) revealed at least (b) (4) unknown peaks; (b) (4) eluting at RT ~ (b) (4) closely to the main peak (b) (4) RT (b) (4) whereas the (b) (4) peak at ~ (b) (4) . These

(b) (4) peaks are not seen in the Method Validation Report No. (b) (4) HPLC/Val (Effective date 12/26/2007) Validation of HPLC Method for the Dissolution of (b) (4) (b) (4) You shipped at least (b) (4) of the tablets that contain unknown peaks to the US customers as summarized in **Table 2**.

Table 2. List of (b) (4) batches with unknown peaks shipped to U.S.

Entry	SFG Batch No. (b) (4)	Batch No.	Number of Tablets	Mfg. Date	Expiry Date	Dispatch Date
(b) (4)						

3. On 11/10/2020, you aborted an analysis for improper peak shape and recorded Analytical Interruption Report No. AIR/20/0170. The improper peak was observed during the dissolution test of (b) (4) (b) (4) USP (b) (4) mg Batch No's: (b) (4) Your investigation reported poor column as the root cause for the improper peak. Based on this, you retested new samples on a different column and invalidated the initial result. However, review of the aborted sample set, (b) (4) revealed that the peak shape for the (b) (4) (b) (4) met the system suitability criteria suggesting that improper p observed during the initial dissolution test was not due to column. Review of the retest analysis of sample sets, (b) (4) revealed at least (b) (4) unknown peaks; (b) (4) eluting at RT (b) (4) as the (b) (4) pea (b) (4) These (b) (4) peaks are not seen in the Method Validatio t No. (b) (4) 120/HPLC/Val (Effective date 12/26/2007) Validation of HPLC Method for the Dissolution of (b) (4) (b) (4) (b) (4) You shipped at least (b) (4) tablets that contain unknown peaks to the US customers as summarized in **Table 3**.

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Table 3. List of (b) (4) batches with unknown peaks shipped to U.S.

Entry	SFG Batch No.	(b) (4) Batch No.	Number of Tablets	Mfg. Date	Expiry Date	Dispatch Date
(b) (4)						

OBSERVATION 2

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

A. You failed to investigate twenty-five (25) equipment failures/errors "Cannot Operate because of failure" observed on 07/21/2022 in the Lab Solutions Ver. 1.108 (data acquisition software) for UV-Visible Spectrometer equipment (ID #QC/UVS/003 and QC/UVS/004) ranging from February 02, 2019 to June 10, 2022 period. The UV-Visible Spectrophotometer is utilized for qualitative and quantitative analysis of drug product and drug substances. Since February 01 2019, the UV-Visible Spectrophotometers have been used to analyze the following products and batches listed below. In addition, you have distributed several batches of the following products into the US Market: (b) (4) Tabs, (b) (4) Tabs, (b) (4) Tabs, (b) (4) Tabs, (b) (4) Tabs USP, (b) (4) Tab USP as summarized in **Table 4** (Table 4 is not all inclusive).

Table 4 - List of Product Analyzed for US Market on UV-Vis ID #QC/UVS/004 & QC/UVS/004

Product Name	B. No.	Indicated Use
(b) (4)		

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(b) (4)

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(b) (4)

[redacted]

B. You have not initiated an investigation for the following equipment failures observed during our inspectional walkthroughs to determine when the malfunction occurred, if the equipment was in use, and perform any impact assessment of the current and previous samples or load ran on the equipment. The equipment below was labeled "Out of Service/ Do not Use".

- (b) (4) [redacted] (ID #QC/ (b) (4) [redacted] 002) placed "Out of Service/ Do not Use" on July

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06, 2022 due to display not working".

- (b) (4) equipment (ID #QC/(b) (4) 009) placed "Out of Service/ Do not Use" on July 20, 2022 due to "Key Panel not working". In addition, you do not maintain an equipment usage logbook for the equipment.

C. We observed the (b) (4) system (ID #QC (b) (4) 003) displayed an error message (b) (4) g our inspectional walkthrough on July 20, 2022. However, you have not taken any actions to address it and your current SOP OC188 Rev 2 (*Operation, maintenance and cleaning procedure of the* (b) (4) does not delineate any provisions for addressing this type of error message. In addition, you do not maintain an equipment usage logbook for the equipment.

D. You failed to investigate alarms observed in the data acquisition system (SCADA) and you do not perform a documented review of the alarm logs and audit trail for the software:

- (b) (4) (Microbiological Lab): (b) (4) Fail, (b) (4) Fail, PLC to SCADA Communication Fail, (b) (4) Fail, (b) (4) Fail, and (b) (4) (b) (4) . The (b) (4) s utilized in Mi

OBSERVATION 3

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

Specifically,

A. You initiated ten (10) Analytical Interruption Reports (AIRs)/ Investigations in the QC Labs.

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However, you have not either started and/or completed these investigation as summarized in **Table 5**. In addition, SOP QC042 Rev. 25 (*Chromatographic and Spectroscopic Analysis and Documentation Practices*) does not include a timeframe for investigation completion.

Table 5 - List of open AIRs Initiated by the firm

AIR Number	Initiation Date	Products/Tests	Closure Date
AIR-22-0278	05/12/2022	(b) (4)	Open
AIR-22-0282	05/14/2022		Open
AIR-22-0331	06/13/2022		Open
AIR-22-0347	06/22/2022		Open
AIR-22-0384	07/08/2022		Open
AIR-22-0390	07/11/2022		Open
AIR-22-0393	07/11/2022		Open
AIR-22-0395	07/12/2022		Open
AIR-22-0400	07/14/2022		Open
AIR-22-0402	02/16/2022		Open

B. You failed to take appropriate corrective measures to prevent recurrence of improper cleaning of UV cuvette (used UV-Vis spectrophotometer (ID #QC/UV/003)) due to lack of awareness for cleaning

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of UV cuvette in case of organic solvents is being used in analysis. You obtained an OOS value of (b) (4) (Specification Limit:- NMT (b) (4) in absorbance test by UV in (b) (4) USP API batch no. (b) (4) for USA market in PR #65425. Based on the reoccurrence trend, you stated this is the fourth (4) incident within 12 months (01/30/2019 to 01/30/2020) for improper cleaning of cuvette (PR #48127, 52694, and 59130). This API batch went into (b) (4) batches of (b) (4) USP finished products released into the US market as summarized in **Table 6**:

Table 6 - List of Finished Products with API Batch (b) (4)

Material Description	Material Batch Number	Used in Finished Product	FP Batch Number	Market
(b) (4)				

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(b) (4)

C. You failed to take appropriate corrective measures to prevent recurrence of power failures of uninterrupted power supply (UPS). You recorded a total of ten (10) power failures where 7 are related to UPS failures in the Quality Control Lab (PR #148042, 154807, 155133, 155403, 155483, 155494, 157215, 158114, 159607, and 160758). You initiated Deviation PR #155483 and DEV-INV-R-0191 to address PR #154807, 155133, 155403, and 155483 which relate to UPS failure in QC Lab. You then initiated initiate CAPA (PR #160572 which is still open) to revise SOP #EN071 to (b) (4) (b) (4) You stated no effectiveness check is required and considered it as an isolated case. You then encountered two more failures of UPS (PR #159607, and 160758).

In addition, you failed to state in the investigations what happened with the products being tested on the equipment and failed to perform appropriate product impact assessment.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. You failed to perform the audit trail reviews for the following data acquisition software utilized in the QC Laboratories. We observed several equipment failures during the inspectional walkthrough on July 21, 2022.

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a. Lab Solutions Ver. 1.108 for UV-Visible Spectrometer (ID #QC/UVS/003 and QC/UVS/004) reflected a total of 25 failures/errors "Cannot Operate because of failure"
b. SCADA (data acquisition software for titrators and autoclave)

B. You have not established a procedure for handling the laboratory incidents. Your Senior Director of Quality Assurance stated that laboratory incidences are handled by SOP No. QC042 R25 (Effective date 12/14/2021) Chromatographic & Spectroscopic Analysis and Documentation Practices. I noted that the procedure (SOP No. QC042) only has directions/instructions for recording the laboratory incidents as Analytical Interruptions (AR). No timelines to complete the ARs and no tools for investigations is available in the procedure (page 65). Also, you have at least 30 open AIRs and 12 of these are open for over (b) (4)

C. You did not follow your procedures, SOP No. QC203 R02 (Effective date 5/20/2021) Handling of Extraneous Peaks in Chromatographic Analysis such that you did not record deviations when extraneous peaks were recorded for the dissolution tests for (b) (4) USP (b) (4) mg Batch No's: (b) (4) The dissolution test revealed at least (b) (4) extraneous peaks including (b) (4) (b) (4) (b) (4) USP (b) (4) mg, (b) (4) mg, and (b) (4) mg that contain extraneous peaks were shipped to US between that are still withing expiry dates.

OBSERVATION 5

Established laboratory control mechanisms are not followed and documented at the time of performance.

Specifically,

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We observed the following during the inspectional walkthrough of the Microbiology and Analytical Laboratories on 07/25/2022 and 07/26/2022 .

A. You failed to record the number of media plates placed into the incubators during growth promotion testing including the incubator number. For example, you performed growth promotion for (b) (4) media Batch (b) (4) which was placed in an unknown incubator. Per y Officer, are required for each bacterial and fungal to be placed in incubators at different ns. However, the Record for Growth Promotion Test of (b) (4) Media does not account for the number of plates placed into the incubators.

In addition, you failed to record in Logbook #2543/22 (Incubator Logbook) the batch number for the media plates placed into the incubators.

B. We observed two balances (ID #QC/WBL/005 and QC/WBL/007) located in the Instrument Lab 4 (Room FQC1003) covered with unknown buildup on the sides inside the weighing area. Your QC personnel could not justify the buildup observed.

OBSERVATION 6

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

A. You failed to document in the batch manufacturing record (BMR) and batch packaging record (BPR) the reasons for any stoppage occurred during the manufacturing and packaging operations in order to effectively conduct thorough investigations. During our walkthrough of your manufacturing and

packaging operations on 07/29/2022, we observed you only document the start and end time in the BMR for [(b) (4)] Tabs. [(b) (4)] mg Batch #[(b) (4)] and BPR [(b) (4)] Batch #[(b) (4)] during the walkthro s on 07/29/20

We reviewed four (4) product complaints for [(b) (4)] (PR #107418, 107618, 140333, 144660) related to broken tablets and short-count for US market as summarized in **Table 7**. Your investigations to these complaints concluded there were no anomalies during the manufacturing and packaging operations. However, we observed on 07/29/2022 during our walkthrough of your manufacturing and packaging operations of that you do not document the reasons for line stoppages in your batch manufacturing and packaging records. [(b) (4)] is [(b) (4)]

Table 7 - List of Complaints for Broken and Short-Count Tablets

PR ID	Product	Batch #	Description
107418	[(b) (4)]		There was one broken tablet in packaging out of the [(b) (4)] tablets of product [(b) (4)] USP [(b) (4)] mg [(b) (4)]
107618			[(b) (4)] sealed boxes that should have [(b) (4)] pills per carton, but only had [(b) (4)] pills per box. [(b) (4)] [(b) (4)]
140333			Complainant observed empty [(b) (4)] in one box of [(b) (4)] [(b) (4)] mg B. No.

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144660	(b) (4)	Pharmacy reporting 1 tablet short in packaging of product (b) (4) (b) (4) USP (b) (4) mg (b) (4)

B. You failed to document in the master batch records for (b) (4) tablet inspection forms (F-QA-0130 and F-QA-0131) the number of tablets collected during the operations as part of the AQL batch size and sample size. For example, we observed in Batch Manufacturing Record - Formulation Order for (b) (4) USP (b) (4) G, Batch (b) (4) that you do not record the n L sam e size (Page 341/393).

***DATES OF INSPECTION**

7/20/2022(Wed), 7/21/2022(Thu), 7/22/2022(Fri), 7/25/2022(Mon), 7/26/2022(Tue), 7/27/2022(Wed), 7/28/2022(Thu), 7/29/2022(Fri), 8/01/2022(Mon)

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