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	9/23/2024-9/27/2024
	FEI NUMBER 3010408344

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Minoo J. Mehta, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Phoenix Innovative Healthcare Manufacturers Private Limited	El - 209 Control Tower, Shil Mahape Road; Electronic Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Navi Mumbai, Maharashtra, 400710 India	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 I OBSERVED:
QUALITY SYSTEM

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate standards, sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically,

A. Your Quality Unit failed to scientifically justify the lack of stability batch testing for batches manufactured under (b) (4) completed process validations, and (b) (4) of those process validations have no stability testing conducted at all.

B. Your Quality Unit failed to initiate, review, and complete a process validation for a change control (CC-PHX-24-113) that required a new pipe to be installed for the transfer of bulk solution from multiple (b) (4) tanks to (b) (4) machine solution tank. There are approximately up to (b) (4) batches of released and distributed drug product within the U.S. Market manufactured under this change. Additionally, your Quality Unit failed to scientifically justify why none of those batches were placed on Stability.

C. Your Quality Unit did not scientifically justify why the QC Manager has full administration privileges for the Gas Chromatography (GC) software, Clarity. During the inspection, I observed that

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EMPLOYEE(S) SIGNATURE
Steven A Brettler, Investigator - GDUFA

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Date Signed: 09-27-2024
10:58:21

DATE ISSUED
9/27/2024

the QC Manager was able to disable elements of the audit trail where a number of changes were not tracked and documented. Additionally, the QC Manager appeared to have full administrative privileges for Chromeleon 7 software for GC as well.

OBSERVATION 2

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,

A. Your Quality Unit failed to document, track, and investigate alert and action limits for (b) (4) testing per your SOP/QC/003 titled "Sampling of (b) (4) ". Per your SOP, (b) (4) excursions would require an investigation and each alert and action limit would be documented within the Out of Alert/Action Limit Log. Upon retrospective review of (b) (4) sampling results from 2022 to present, there were approximately 138 identified alert/action limit excursions not documented with approximately six (6) instances of (b) (4) alert/action limit excursions that should have been investigated.

B. Your Quality Unit failed to investigate the Out-of-Specification (OOS) for the reconciliation yield for (b) (4) caps within (b) (4) lot (b) (4) despite documenting (b) (4) as Out-of-Specification within the manufacturing batch record.

C. Your Quality Unit failed to thoroughly investigate complaints without attempting to collect any physical samples. Your SOP, QSP/QA/013 titled "Customer Complaints" fails to require an attempt or multiple attempts to collect the complaint sample for the investigation.

D. Your Quality Unit failed to document, track, and investigate each instance of damaged and repackaged outer boxes when drug products are returned from terminal sterilization via (b) (4)

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(b) (4) Even though there appears to be a damage report, each event is not documented as a non-conformance for rework (repackaging) and appropriately investigated and/or tracked for trends. Upon a retrospective analysis during the inspection, there are approximately 234 instances where a non-conformance should have been investigated.

OBSERVATION 3

Reserve drug product samples are not retained and stored under conditions consistent with product labeling.

Specifically,

During the facility walkthrough on 09/25/2024, I observed the reserve sample area within an uncontrolled environment where there was no temperature mapping completed for the designated area, and the temperature being recorded (b) (4) does not include the highest and lowest temperatures for (b) (4) There is no data available to provide assurance that the retains were stored within an environment as specified per the drug products' labeling.

PRODUCTION SYSTEM

OBSERVATION 4

Deviations from written production and process control procedures are not recorded and justified.

Specifically,

During document review on 09/23/2024, I observed Out-of-Specification (OOS) OOS/22/002 for a stability sample failure for (b) (4) lot (b) (4) Upon closer inspection, there was not adequate documentation available to determine if any of the batch was distributed within the U.S. Market. Upon investigation by your Quality Unit during the inspection, multiple deviations were

identified:

-The batch that failed was not part of the commercial batch (b) (4), but rather, it was a trial batch for (b) (4) without the appropriate batch identification numbering for trial batches.
-No records were kept at any stage during (b) (4) production.
-No records were kept of destruction of both the rejected (b) (4) and trial (b) (4)
-Batch Manufacturing Records (BMRs) were not prepared for the trial of (b) (4)

OBSERVATION 5
Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of holding of the drug product.

Specifically,

There is no yield reconciliation calculated and assessed when each drug product that undergoes terminal sterilization via (b) (4) is returned to the facility, and the outer boxes are found to be damaged and replaced by repackaging (rework) as documented within the production batch record for each impacted drug product batch.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 6
Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and suitably located to facilitate operations for its intended use.

Specifically,

During the facility walkthrough on 09/25/2024, I observed droplets of unidentified liquid on both the

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floor and corners of the viewing window of the (b) (4) stability chamber for accelerated studies (Equipment ID: QA-299). The unidentified liquid appears to have originated from an external tubing connected outside the unit that may have allowed liquid to flow back into the stability chamber instead of outside the unit; however, there is/are no probable root cause(s) identified and provided by your Quality Unit during the time of inspection.

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	Steven A Brettler, Investigator - GDUFA X Steven A Brettler Investigator - GDUFA Signed By: Steven A. Brettler -S Date Signed: 09-27-2024 10:58:21	9/27/2024