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	3/27/2022-4/1/2022
	FEI NUMBER 3015523180

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. A.B.M Mahfuz ul Alam Ph.D, Director, Quality Operations

FIRM NAME	STREET ADDRESS
ACI HealthCare Limited	Sonargao, Road No 1, Tripurdi
CITY, STATE, ZIP CODE, COUNTRY Narayanganj, 1440 Bangladesh	TYPE ESTABLISHMENT INSPECTED Finished 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:

OBSERVATION 1

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

The quality unit lacks authority to fully investigate data integrity events that have occurred in the laboratory. Investigations do not always include complete data derived from all tests necessary to assure compliance with established procedures. For Example, during my review of data on your (b) (4) analyzer equipment, I observed testing performed in October 2020 by your analyst in the October 2019 folder. (b) (4) testing for (b) (4) was performed on 10/13/2020 starting at 11:47 am, with results for (b) (4) generation system and (b) (4) distribution system with OOS results. Per the analyst, an investigation was initiated. Next, the analyst performed testing using the same vials later in the evening on 10/13/2020 starting at 4:39 pm in the October 2019 folder and confirmed the OOS results. Per the investigation, the location for sample was cleaned, and (b) (4) samples were taken and tested on 10/14/2020 starting at 11:51 am with passing results. During review of the investigation report and analytical batch records (data package), I did not observe the data package or any reference to the 10/13/2020 confirmation testing performed in the October 2019 folder. Your firm's Quality Unit was not aware of this additional test and data. This discrepancy in your firm's ability to review and investigate all electronic data is a gap in your firm's Data Integrity program.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre	X Arsen Karapetyan Investigator - Dedica ed Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 0 -01-2022 10:25:19	4/1/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/27/2022-4/1/2022
	FEI NUMBER 3015523180

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. A.B.M Mahfuz ul Alam Ph.D, Director, Quality Operations	
FIRM NAME ACI HealthCare Limited	STREET ADDRESS Sonargao, Road No 1, Tripurdi
CITY, STATE, ZIP CODE, COUNTRY Narayanganj, 1440 Bangladesh	TYPE ESTABLISHMENT INSPECTED Finished Drug Manufacturer

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

Your Quality Unit has not performed the necessary assessments/reviews to ensure that objectionable conditions do not negatively affect Quality Control testing operations performed by your laboratory. Specifically,

A. Dedicated Quality Assurance (QA) personnel in the Quality Control Laboratory (QC) perform (b) (4) reviews related to general data integrity principles. These responsibilities and procedures applicable to review activities performed by QA personnel for testing operations in QC and Computer Software Systems are not in writing.

B. Electronic data from previous years and quarters stored in folders on standalone and network systems such as (b) (4) UV-VIS, ICP-OES, and HPLC are not locked. Analysts are free to start, perform, and save testing in all folders. During review of data for (b) (4) testing, I observed testing performed in 2020 by your analysts in the October 2019 folder. The ability for analysts to perform testing in past folders is a gap in your Data Integrity Program.

C. The Quality Control Laboratory does not have an established naming convention naming sample solutions in standalone and network software systems. For example, I observed different naming formats used by two different analysts for samples tested via HPLC.

D. QC review of chromatographic and non-chromatographic electronic raw data generated by analysts in the QC laboratory is not adequate. QC supervisors responsible for electronic data review do not perform a comprehensive review of all potential electronic data generated for all test items in your standalone and network systems.

E. There is no adequate data integrity program in place to include statistically sound comprehensive review of electronic data by the Quality Unit for standalone and network systems, to ensure

completeness, consistency, and accuracy of all chromatographic and non-chromatographic electronic raw data generated by the Quality Control Laboratory.

OBSERVATION 3

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

Investigations initiated and performed by your Quality unit in response to out-of-specification test results related to testing for exhibit batches manufactured in support of your [(b) (4)] applications are not always scientifically sound or comprehensive. Specifically, Corrective Action/P tive Action (CAPA's) as a result of investigations were not always comprehensive to address root causes or adequately documented to have been performed.

-OOS/19/001, dated 07/17/2019, initiated due to OOS for unknown impurity and [(b) (4)] during [(b) (4)] Accelerated Stability study for [(b) (4)] Tablets USP [(b) (4)] mg and [(b) (4)] mg, batch numbers [(b) (4)] Corrective Actions to be perf ed were listed in the OOS investigat ed to initiated and track completion of CAPA items.

-OOS/20/016, dated 05/09/2020, initiated due to OOS result for unknown impurity during [(b) (4)] ccelerated stability study for [(b) (4)] ablets USP [(b) (4)] mg and [(b) (4)] mg, batch numbers [(b) (4)] and 12M intermediate and long-term stability study for batch numbers [(b) (4)] Corrective Actions to be performed were listed in the OOS investigation report. No official CAPA was initiated to initiated and track completion of CAPA items.

-MOOS/20/002, dated 01/23/2020, initiated due to OOS for microbial limit test for [(b) (4)] for [(b) (4)] Tablets [(b) (4)] mg batch [(b) (4)] Testing was part of a hold time study for [(b) (4)] with

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/27/2022-4/1/2022
	FEI NUMBER 3015523180

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. A.B.M Mahfuz ul Alam Ph.D, Director, Quality Operations

FIRM NAME	STREET ADDRESS
ACI HealthCare Limited	Sonargao, Road No 1, Tripurdi
CITY, STATE, ZIP CODE, COUNTRY Narayanganj, 1440 Bangladesh	TYPE ESTABLISHMENT INSPECTED Finished Drug Manufacturer

(b) (4) testing withing specification, and (b) (4) testing OOS. The investigation revealed that the probable root cause was due to contamination, without a scientifically sound or comprehensive root cause analysis. CAPA listed in the report was to perform a hold time study before commercial manufacturing commences, which does not address any potential root causes for MOOS/20/002.

-OOS/20/038, dated 08/03/2020, initiated due to OOS for unspecified impurity for (b) (4) USP (b) (4) mg. Investigation determined that the analyst misidentified a diluent peak, which you firm documented as being observed in the method validation. No adequate CAPA was initiated as a result of the firm's findings, in that the standard test method (STP) procedure was not updated to mention the diluent peak observed in the method validation.

-OOS/20/044, dated 08/27/2020, initiated due to OOS for (b) (4) est for hold time study for (b) (4) Tablets (b) (4) mg batch number (b) (4) Investigation determined the root cause to be improper material handling during sampling and laboratory test, without a scientifically sound or comprehensive root cause analysis. No consideration was given to the amount of time in between sample receipt and (b) (4) test performed, which was (b) (4) Additionally testing performed with passing results were tested with (b) (4) and (b) (4) in between sample receipt and (b) (4) test.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre	X Arsen Karapetyan Investigator - Dedica ed Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 0 -01-2022 10:25:19	4/1/2022