

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
CDER/International Compliance Team 10903 New Hampshire Ave., Bldg. 51, Rm. 4225 Silver Spring, MD 20993 U.S.		August 16 - 19, 2016
Industry Information: www.fda.gov/oc/industry		FEI NUMBER
Tel: 001-301-796-3334 Fax: 001-301-847-8738 Email: cderict@fda.hhs.gov		3004058356

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Deepak Rawat, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Badrivishal Chemicals & Pharmaceuticals	Gat.No. 29, Village Jambwade, Post Sudumbre, Taluka Maval
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dist. Pune 412109, India	Drug Substance Manufacturer

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

QUALITY SYSTEM

OBSERVATION 1

Appropriate controls are not exercised to assure that changes to documents related to the manufacture of intermediates or APIs are instituted only by authorized personnel.

Specifically,

- 1) Although required by Sections 5.3-5.5 and 5.13-5.14 of SOP QAD/002/01 (eff. 10JAN2016),
 - no registers documenting the original issuance of controlled documents, to include batch manufacturing records, analytical test reports, and analytical worksheets, are maintained;
 - there are no features or mechanisms to distinguish between original and unauthorized re-prints/copies of controlled documents;
 - and there is no means of reconciling the quantity of working copies of each controlled document issued for a given production batch, analysis, or time period.
- 2) On 16AUG2016, an uncontrolled, serialized stamp was found in the Quality Control (QC) Laboratory. This serialized stamp is used by the QA department to sequentially number pages in controlled equipment laboratory equipment usage logbooks.

LABORATORY CONTROLS SYSTEM

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	 Patric C. Klotzbuecher, Investigator Daniel J. Roberts, Investigator	19 AUG 2016 19 AUG 2016	19AUG2016

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OBSERVATION 2

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

Specifically,

1) The review of torn, discarded records recovered from refuse in the plot adjacent to the south/southeast of the facility identified the following:

A) In-process test sheet used for sample collection intimation for (b) (4) Crude Stage (b) (4), dated 14AUG2016.

Discrepancies in product name were discovered upon comparison to that reported on the official version of the corresponding record.

B) Form QCD-F-00-059, Analytical Test Report of in-process material, and analytical worksheet corresponding to testing conducted according to STP/IPQC/(b) (4) /02/00, issued on 07JUN2016.

Official versions of the corresponding records consist of appearance and moisture content test data for Batc (b) (4) of (b) (4) following Step (b) (4) (b) (4).

C) Analytical test report of finished API (b) (4) Batch (b) (4), dated 14APR2016.

Discrepancies in hand-written entries for solubility testing for the batch were identified upon comparison to the values reported on the official version of the corresponding record.

D) Analytical worksheet dated March 20, 2016, consisting of hand-written calculations for residue on evaporation and microbiological test results.

E) Form QCD-F-006-00, Analytical Test Report of (b) (4) Water corresponding to Analytical Report

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	<i>P.C.R. in lieu of P.J.R.</i>	Daniel J. Roberts, Investigator	

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(b)(4)/514/2015-16, issued on 20MAR2016.

The official version of the corresponding test report consists of data for the 20MAR2016 (b)(4) water sample from (b)(4) stating that "The Sample complies with Inhouse Specification". Review of the (b)(4) water/potable water Inward Register", Registry QCD-R-003-00, identifies a single (b)(4) water sample from (b)(4) received and analyzed by QC on 20MAR2016 as "Not OK", yet the fragment of an additional hand-filled copy of the analytical report for a (b)(4) water sample from (b)(4) also issued on 20MAR2016 was recovered from the refuse.

F) Water testing results for samples collected from sample point (b)(4) on 30MAR2016 and analyzed on 04APR2016.

G) Form QCD-F-006-00s, Analytical Test Report of (b)(4) /Potable Water, corresponding to Analytical Reports (b)(4)/069/2016-17 and PTW/009/2016-17, completed on 09APR2016.

Fragments of numerous copies of Analytical Test Reports consisting of original, hand-written test data were recovered from refuse, two of which with similar tear patterns identify analyses completed on 09APR2016 by the same analyst. One of the two fragments documenting analysis on 09APR2016 indicated that results did not comply while the other indicated compliance with specifications. A third, undated and unsigned fragment of what appeared to be the same Analytical Test Report with the same tear pattern contains hand-written data but no determination of compliance. Formatting of the official version of AR(b)(4)/069/2016-17 for (b)(4) water testing from the firm's (b)(4) on 09APR2016 is consistent with the discarded fragments indicating analysis on 09APR2016 and compliance with specifications.

H) Form QCD-F-006-00, Analytical Test Report of (b)(4) Water, and analytical worksheet for testing from sample point (b)(4), completed 30MAY2016.

The official version of Analytical Test Report (b)(4)/203/2016-17 consists of data for the 30MAY2016 (b)(4) water sample from (b)(4) (b)(4) of the (b)(4) water (b)(4). Values from the visible portions of the analytical results for pH, Ammonium, and Residue on Evaporation testing differ between the discarded and official versions of A.R. (b)(4)(b)(4) 203/2016-17.

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	J.C.R. in lieu of D.S.R. JAN2016		

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I) Temperature and Relative Humidity Records for Control sample room for the month of July 2016.

Discrepancies in relative humidity entries were discovered when comparing the values reported on the official record and the discarded record found in the trash area.

J) Form QCD-F-009-01, ^{(b) (4)} Calibration Record of Shimadzu Balance QCD/WB/01, for August 2016.

The corresponding version observed in use at the time of inspection of the QC lab documents standard weight calibrations conducted 04-16AUG2016. Fragments of two pages of the Form QCD-F-009-01 recovered from the refuse identify original, hand-written values of standard weight calibrations performed 01-09 and 12-14AUG2016 which differ from those reported in the version in use at the time of inspection.

No formal justification or investigation of the discarded "controlled copies", unreported test data, environmental monitoring, or equipment calibration records were documented and the results of each discarded record were not included in the review and disposition of affected samples.

2) Chromatographic data for impurity testing of ^{(b) (4)} consists of incomplete data for review and approval of batches for commercial release. Printed chromatograms and data generated by a contract testing laboratory for the following batches fail to include complete information for the impurity testing performed such as full sequences of injections, original and reprocessed data sets, and explanations for aborted sequences:

- Batch ^{(b) (4)} (A.R. FP ^{(b) (4)} 058/2015-16), released 30NOV2015,
- Batch ^{(b) (4)} (A.R. FP 059/2015-16), released 01DEC2015,
- Batch ^{(b) (4)} (A.R. FP 060/2015-16), released 05DEC2015,
- Batch ^{(b) (4)} (A.R. FP 070/2015-16), released 06JAN2016,
- Batch ^{(b) (4)} (A.R. FP ^{(b) (4)} /013/2015-16), released 10JAN2016,
- Batch ^{(b) (4)} (A.R. FP ^{(b) (4)} 073/2015-16), released 14JAN2016.

OBSERVATION 3

Laboratory control mechanisms are not scientifically sound and appropriate to ensure that raw materials,

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intermediates, and APIs conform to established standards of quality and/or purity.

Specifically,

- 1) Growth promotion testing of media prepared in-house is routinely performed using a single test organism rather than according to compendial requirements. For example, (b) (4) (b) (4) plate Batch (b) (4) was used to perform microbial enumeration tests and testing for the presence of a variety of specific pathogens for (b) (4) water system validation samples collected on 07MAR2016. Yet growth promotion testing of Batch (b) (4) was performed using an inoculum of Salmonella abony (6017 NCTC) only.
- 2) The temperature of media is not monitored during media batch preparation.
- 3) Actual temperatures of the 20-25°C incubator used for fungal plate incubation, equipment ID MIC/TNC/01, and the (b) (4) °C incubator used for E. coli test plate incubation, equipment ID MIC/TNC/03, are not recorded.

OBSERVATION 4

Computerized systems do not have sufficient controls to prevent unauthorized access or changes to data.

Specifically, unique user identifications have not been established for computerized systems used in the QC Laboratory. All personnel share the "Administrator" user name and password to log into and perform commercial release testing using chromatographic instrumentation. Furthermore, the "Administrator" user has unrestricted system and software privileges that allow for the deletion, modification and alteration of raw chromatographic data.

OBSERVATION 5

Test procedures are not fully documented at the time of performance.

Specifically,

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- 1) On 12JUN2016, five (5) injection sequences were performed for ^{(b) (4)} solvent testing on Gas Chromatography instrument GC-01 corresponding to the following data files: 001.rslt, 002.rslt, 003.rslt, 005.rslt, and 007.rslt. However, the running of these sequences for unidentified batches of raw material was documented in the equipment usage logbook for GC-01.
- 2) Review of chromatographic source data identified sequences for impurity testing of ^{(b) (4)} run on 02FEB2015, 21FEB2015, 26SEP2015, and 06JAN2016. However, the running of these sequences for various batches of finished drug substances was not documented in the equipment usage logbooks for HPLC-01.
- 3) Review of the analytical worksheets for microbiological testing in support of the ^{(b) (4)} Water system performance qualification (samples collected from 07MAR-05APR2016) identified numerous failures to document the batch #'s of media used for pathogen testing and analysts and secondary officials responsible for test execution and review, respectively.

OBSERVATION 6

Complete records documenting the suitability of compendial test methods are not maintained.

Specifically, compendial method verification studies are not available for residual solvent, impurity, and microbiological test methods used for the testing and release of commercial batches of ^{(b) (4)}, USP, drug substance by an off-site, contract testing laboratory.

OBSERVATION 7

Out-of-specification results are not thoroughly investigated in that assessments of whether significant problems exist, allocation of the tasks for corrective actions, and conclusions are not documented.

Specifically, no investigations or determination of root causes for the two (2) out-of-specification (OOS) results generated in 2015 and 2016 were documented. These two (2) OOS results for rejected raw material batches consist of the following:

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- OOS/001/2016-17 for (b)(4) raw material Batch (b)(4), dated 11JUN2016, for appearance/description;
- OOS/001/2015-16 for (b)(4) raw material Batch (b)(4), 03AUG2015, for loss-on-drying.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 8

Water used in the manufacture of APIs has not been demonstrated to be suitable for its intended use.

Specifically,

- 1) Installation and operational qualification of the current (b)(4) water system was completed in December 2011 and the system has been in continuous use for manufacturing and cleaning activities since then. However, performance qualification of the (b)(4) water system was not initiated until 16 months later, with initiation of Validation Protocol VP/PFD-02/001/00 on 07MAR2016.
- 2) Source water emanates from a nearby river (~1km from the facility), and is not subjected to governmental testing for potability. No microbiological testing of source water from the primary storage tank is performed to verify its suitability according to World Health Organization (WHO) guidelines for potability.
- 3) Validation Protocol VP/PFD-02/001/00 requires no microbiological testing of source water to evaluate the total coliform load introduced to the water purification system or to demonstrate effective reduction of total coliform loads throughout seasonal variations.
- 4) During execution of the initial phase of the (b)(4) water system performance qualification (07MAR- (b)(4) samples from all points (b)(4) Sanitization, (b)(4) through (b)(4) failed to meet acceptance criteria for microbial load of (b)(4) water. Additionally, (b)(4) samples from sampling point (b)(4), (b)(4), and (b)(4) also failed to meet acceptance criteria for chemical characteristics of (b)(4) water. However, (b)(4)

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(b) (4) interim Validation Report VR/PFD-02/001/00 (eff. 11APR2016) states that (b) (4) chemical and microbiological test results were within acceptance criteria for all sample points during the initial phase of validation.

5) Per SOP MTN/004/00 (eff. 01OCT2015),

A) Sanitization of the (b) (4) Water system is to be performed (b) (4) (every (b) (4) at a (b) (4) of (b) (4) for (b) (4).

Review of the most-recent sanitization cycle run 15AUG2016, documented on Form MTN-F-005-00, identified maintenance of the (b) (4) sanitizing (b) (4) for 15min. instead of the (b) (4) required. Further review of the documentation of sanitization cycles run since January 2016 identified maintenance of the sanitizing (b) (4) for less than the (b) (4) required on eight (8) different occasions. Additionally, no sanitization cycle was documented between 11JAN and 26FEB2016. As of the time of inspection, no deviation was initiated for these excursions from SOP MTN/004/00.

B) Following sanitization, the (b) (4) water storage tank and distribution loop are to be (b) (4) (b) (4) and at that time sampled from the (b) (4) of the (b) (4) water (b) (4) (b) (4)

From January 2016 to present, routine (b) (4) water microbiological sampling coincides with the (b) (4) frequency for (b) (4) water system sanitization on 2 occasions (11JAN and 02MAY2016). As such, sampling from (b) (4) immediately following the sanitization cycle was not truly representative of the microbial quality of (b) (4) water used in manufacturing and cleaning activities over the periods of (b) (4) -11JAN2016 and (b) (4) -02MAY2016.

6) SOP QCD/003/00, "Standard Operating Procedure for Sampling and Chemical Analysis of Potable Water and (b) (4) Water" (eff. 28JUN2013), requires water samples to be collected from the user points located the production area. However, all water samples collected for chemical and microbiological analysis prior to March 2016 were sampled solely from the (b) (4) of the (b) (4) water (b) (4) (b) (4) sampling point (b) (4).

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- 7) The (b) (4) water storage tank used to collect, pool, and re-circulate (b) (4) water to points-of-use throughout the API production area is not equipped with a vent filter. Upon inspection, a gap was observed between the tank housing, its gasket, and its manhole cover with fasteners missing from the cover. The interior of the (b) (4) water storage tank was directly exposed to the surrounding, uncontrolled environment through the gap and condensation was observed settling along the interior rim of this gap.
- 8) The in-line conductivity and flow meters used to monitor the conditions of the (b) (4) water system are not routinely calibrated. Furthermore, there is no SOP describing the usage of or established acceptance criteria for each measurement device.

OBSERVATION 9

Adequate, clean washing and toilet facilities are not provided for personnel.

Specifically, soap or detergent and air driers or single service towels are not provided at hand or foot washing facilities used by manufacturing personnel immediately prior to gowning and entry into production areas with open, exposed toe sandals.

*D.C.K.
19 AUG 2016*

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