DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration/ CDER- Office of Compliance HFD-325 10903 New Hampshire, W051, Room 4225 Silver Spring, MD 20993 Attn: Foreign Inspection Team Phone: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	December 7, 2015-December 15, 2015
	FEI NUMBER 3002808500

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Udaykumar Rakibe, Senior Vice President Quality

FIRM NAME	STREET ADDRESS
Wockhardt Limited	Plot No 138, G.I.D.C. Industrial Estate
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
District: Bharuch, Ankleshwar, Gujarat, 393002 India	Active Pharmaceutical Ingredient Manufacturing Facility

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

QUALITY

Observation 1

Record entries documenting your operations shall be made contemporaneously and permanently in spaces provided for such entries, and should identify the person making the entry.
Corrections to entries shall be dated and signed and leave the original entry still legible and preserved.

Specifically,

A) I did not observe Quality Unit oversight/approvals required for the destruction and incineration of documents. For example on December 7, 2015, the following records were discovered torn/shredded in the scrap yard area awaiting incineration:
i. Raw Material label for (b) (4) batch (b) (4) dated October 30, 2015
ii. Maintenance Work Order Permit for repairing leakage from (b) (4) gasket of (b) (4) located in (b) (4) area dated November 2, 2015
iii. Engineering Contractor Hot Work Permit for dismantling and cutting unwanted line for reactors removed from production building (b) (4) area dated October 7, 2015

B) On December 7, 2015 during a walk-through of the Process Development Laboratory, an uncontrolled private/ personal diary was discovered containing experimental protocol laboratory data. The Process Development Laboratory is used to conduct experimental quality failure investigation sample preparations, route of synthesis, and scale-up process related laboratory testing. Entries in the uncontrolled private/personal diary included calculations, molecular weights and experimental details and data.

LABORATORY

Observation 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not

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	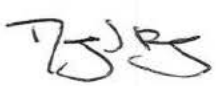	Daniel J. Roberts, Investigator	12/15/2015

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established.

Specifically,

A) Aseptic Media Fill "Report for Aseptic Process Simulation by Piggyback Media Fill Method of Sterile Plant (b) (4) ' VP (b) (4) APV/R-6 effective October 15, 2015 explains that the media fill sterility testing for the Aseptic processing area was performed using (b) (4) finished sterile API containers filled during the media fill. The remaining (b) (4) finished sterile API filled containers were sampled but not tested for sterility and were retained for failure investigation purpose only.

B) You did not identify worst-case locations on equipment and processing areas for microbial environmental swabs and microbial contact plates inside the sterile production area in building (b) (4) that is used to manufacture Sterile (b) (4) USP and Sterile (b) (4) Active Pharmaceutical Ingredients.

C) On December 10, 2015 during a walk-through of the sterile manufacturing block (b) (4) I observed that three (3) out of ten (10) sterile gowns, which had been quality checked for acceptance in the sterile area had unraveled stitching threads extending from the hood, zipper and pants on the gown. The thread fiber lengths were between 1cm and 3cm. One (1) of the three (3) sterile gowns had shredded boot strap ties with thread fiber lengths in excess of 10cm. Sterile manufacturing block (b) (4) s used for the manufacturing of Sterile (b) (4) USP and Sterile (b) (4) Active Pharmaceutical Ingredients.

D) For the (b) (4) facility environmental monitoring, I did not observe any traceability when the (b) (4) environmental isolates were recovered from the production area. Furthermore, for up to (b) (4) all of the (b) (4) microbial culture (b) (4) created from the (b) (4) microorganisms were being stored in the same bag together corresponding to the (b) (4) of use.

E) I observed operator interventions including hand movements interfering with the unidirectional flow of smoke for aseptic connections of (b) (4) between the (b) (4) and (b) (4) of (b) (4) performed inside the Laminar Air Flow LAF-712. These operator interventions were observed during review of the unidirectional airflow smoke study simulation "Report for Unidirectional Air Flow Visualization in Dynamic Condition" VP (b) (4) /GRADE A Air Flow Visualization/R2 dated October 12, 2015.

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Observation 3
Computerized systems shall have sufficient controls to prevent unauthorized access or changes to data.

Specifically,

A) Prior to July 25, 2014, Quality Control Analysts had the ability to delete raw data files from Gas Chromatograph instrument ID QA/G07 used in the (b) (4) manufacturing facility for testing residual solvents for finished APIs and Raw Materials.
B) The following Gas Chromatograph injections were performed but the firm did not maintain any supporting documentation why these injections occurred.

i. On January 26, 2013, three (3) injections of Raw Material (b) (4) tanker truck Batch (b) (4) and solvent tank FNR10062 samples were performed corresponding to injection file E:\JAN13G07\DATA\(b) (4) _2601 \(b) (4) 01.D;(b) (4) 02.D and (b) (4) 03.D.
Gas Chromatography Injection file E:\JAN13G07\DATA\(b) (4) _2601\(b) (4) _01.D was performed on January 26, 2013 at (b) (4) and corresponds to Raw Material (b) (4) tanker truck Batch (b) (4) with a passing result purity of (b) (4) % (Specification NLT (b) (4) %)
Gas Chromatography Injection file E:\JAN13G07\DATA\(b) (4) _2601\(b) (4) _03.D was performed on January 26, 2013 at (b) (4) and corresponds to Raw Material (b) (4) solvent tank Batch (b) (4) with a failing result purity of (b) (4) % (Specification NLT (b) (4) %)
Gas Chromatography Injection file E:\JAN13G07\DATA\(b) (4) _2601\(b) (4) _02.D was performed on January 26, 2013 at (b) (4) and corresponds to Raw Material (b) (4) solvent tank Batch (b) (4) with a passing result purity of (b) (4) % (Specification NLT (b) (4) %)
However, only injection ((b) (4) 02.D) was officially reported for Raw Material (b) (4) solvent tank Batch (b) (4) without any documentation explaining why the failing injection result for ((b) (4) 03.D) was excluded from the analysis.

ii. On January 21, 2013 at (b) (4) a single injection of a sample labeled as (b) (4) Residual Solvent (b) (4) injection file: D:\JAN13G07\DATA\DEFAULTB.D was performed. (b) (4) (b) (4) Residual Solvent (b) (4) was previously analyzed and released in December 2009. However, this single injection performed on January 21, 2013 at (b) (4) for (b) (4) was

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not reported.

On January 21, 2013 at (b) (4) in-process (b) (4) batch (b) (4) sample 1 for Residual Solvent (b) (4) under injection file: D:\JAN13G07\DATA\(b) (4) 2101(b) (4))004.D was performed and reported.

On January 21, 2013 at (b) (4) in-process (b) (4) batch (b) (4) sample 2 for Residual Solvent (b) (4) under injection file: D:\JAN13G07\DATA\(b) (4) 101(b) (4))005.D was performed and reported.

iii. On May 8, 2014, three (3) injections of (b) (4) Batch (b) (4) in-process residual solvent (b) (4) samples were performed corresponding to injection file C:\DATA\MAY_2014_G06\DATA\StE. (b) (4) _0805\ste(b) (4) _0805_008.rst; _009; and _010. However, only two (_008.rst and _009.rst) out of these three injections (_008.rst; _009.rst; and _010) were officially reported without any documentation explaining why the injection (_010) was excluded from the analysis.

iv. On May 7, 2013 at (b) (4) Residual Solvent Analysis for (b) (4) njection was initiated under sample set file: C:\DATA\WOCKHARDT\MAY_2013_G06\DATA\(b) (4) _C_0705 for sample name PD (b) (4) _A and PD(b) (4) _B. There is no corresponding documentation or Process Development Experimental Protocol/Report describing the purpose of these injection samples.

Observation 4

Computerized systems shall be validated and the depth and scope of the validation depends on the diversity, complexity, and criticality of the computerized application. In addition, appropriate installation and operational qualifications shall also demonstrate the suitability of computer hardware and software to perform assigned tasks.

Specifically,

The following twelve (12) computerized system and instrument software used in the quality testing laboratory that are currently in use for routine testing have not been validated:

Instrument	Name Software	Date of Installation in Laboratory
FTNIR	Omnic 9.2.86	June 18, 2015
Stability Chambers	Newtronic IC DAS 1.2	May 29, 2015
TOC-L	TOC Control L 1.02	July 25, 2015

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LBPC	Pharm Spec Ver. 3	June 25, 2015
Polarimeter	Spectra Manager 2.10.01	July 8, 2015
Perkin UV	UV Win LabES 6.0.4	July 21, 2015
TOC-V	TOC-V 2.10	July 27, 2015
FTIR	Omnic 9.3.32	August 4, 2015
Perkin UV	UV Win Lab ES 6.0.4	July 23, 2015
FTIR	Shimadzu IR Solution 1.30	September 4, 2015
Malvern	Malvern Master Sizer5.61	August 7, 2015
TLC	WinCats 1.4.9.2001	September 10, 2015

Observation 5
Proposals for GMP relevant changes shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality unit.

Specifically,

A) On October 14, 2015, a change in quality testing laboratories occurred and a change control was not initiated and reviewed by the quality unit. On this date (b) (4) USP Finished API batches (b) (4) and (b) (4) were sent to a different contract testing laboratory to conduct routine quality release testing of Polymorphism by X-Ray Diffraction (XRD) (MOA-300937-02-2).

B) On July 28, 2015, Total Organic Carbon (TOC) instrument ID QAI/T02 computer system hard drive and instrument software was removed from the laboratory and a new hard drive and instrument software version was installed. On December 7, 2015, there was no entry in the TOC instrument ID QAI/T02 equipment logbook discussing this change in computer system hard drive and instrument software. Furthermore, change control (CC/AN-QC/15-092) associated with changing non-chromatographic laboratory computer system hard drives and instrument software versions does not discuss the quality testing laboratory instruments that are affected by this change.

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Observation 6

Deviations from approved standards of calibration on critical instruments shall be investigated to determine if these could have had an effect on the quality of the intermediate(s) or API(s) tested since the last successful calibration.

Specifically,

On January 10, 2015, the Total Organic Carbon Analyzer instrument QAI/T03 that was used to test (b) (4) and (b) (4) Water samples failed Calibration acceptance criteria for Standard Deviation value of (b) (4) (Specification < (b) (4) and Coefficient Variation value of (b) (4) % (Specification < (b) (4) %). However, an assessment was not performed to evaluate if the calibration failure had any impact on the samples tested on the instrument since the previous passing calibration.

Observation 7

Analytical methods shall be validated to include consideration of the characteristics included in the validation of analytical methods. The degree of analytical validation performed shall also reflect the purpose of the analysis and the stage of the API production process.
Specifically,

On December 8, 2015, (b) (4) USP Finished Active Pharmaceutical Ingredient in-house developed test method Polymorphism by X-Ray Diffraction (XRD) (MOA-300937-02-2) that is used for the identification of the finished API had not been validated.

FACILITIES AND EQUIPMENT
Observation 8

Buildings and facilities used in the manufacture of intermediates and APIs should be constructed to facilitate

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cleaning, maintenance, and operations as appropriate to the type and stage of manufacture and to minimize possible contamination from equipment.

Specifically,

A) On December 9, 2015, during a walk-through of the Production Block (b) (4) finished dosage (b) (4) API manufacturing facility, I observed rust, flaking and chipping paint on the (b) (4) for (b) (4) as well as the ceiling and overhead I-beams that are located directly above the (b) (4) covers that are opened for (b) (4) of materials into the (b) (4) used during the (b) (4) Stage and (b) (4) (b) (4) Stage manufacturing process for (b) (4) API.

B) On December 9, 2015, during a walk-through of the (b) (4) Water Unit (WU) that supplies (b) (4) water to Production Block (b) (4) I observed incoming treated water leaking from the top gasket and onto the floor from the (b) (4) tank. This (b) (4) water generated inside the (b) (4) Water Unit (WU-(b) (4)) is used in the manufacture of (b) (4) different finished Active Pharmaceutical Ingredients in Production Block (b) (4) including (b) (4) API.

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