DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	03/16/2015 - 03/20/2015 FEI NUMBER 1000110912

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Christopher W. Gregory, Ph.D., General Manager

FIRM NAME	STREET ADDRESS
Catalent Pharma Solutions LLC	160 North Pharma Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morrisville, NC 27560	Drug Manufacturer and Control Laboratory

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

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

Specifically,

(a) Batch production records are not issued according to SOPs PDR-DOC-0024, PDR-PPG-0014 and PDR-DOC-0020. Firm management stated batch records are printed from (b) (4) and then a photocopy is distributed to manufacturing. The reason for this is to allow issuance of additional pages by the (b) (4) as needed. On 03/18/14 while reviewing the batch number (b) (4), one of (b) (4) registration batches for (b) (4) (b) (4) we observed pages 2, 9, 10, 29A, 30A, and 31A were inconsistent with the rest of the batch record (different paper type and (b) (4)). No explanation was documented, or provided during the inspection as to when, why or how pages 2, 9 and 10 were replaced. Additionally, pages 30A added to batch record (b) (4) and pages 29A, 30A, and 31A added to batch record (b) (4) were not (b) (4) as required by procedure.

(b) On June 10th 2014, your contractor (b) (4) performed a calibration on equipment bearing identification EQP-M0020, (b) (4) Checkweigher used in manufacturing. However,your QA department reviewed the document on March 19th 2015, during the FDA audit, almost 9 months after the calibration was performed.

(c) On November 13th 2014, your firm completed a "Campaign" cleaning of the (b) (4) manufacturing equipment PBR# 14MM-049, post production. Then on November 19th 2014, your firm performed an "In-process" cleaning of the same equipment. However, your QA department reviewed the cleaning performed on November 13th 2014 on January 30th 2015 and the cleaning performed on November 19th 2014 on January 29th 2015, respectively. This indicates that your QA department did not review the completed cleaning batch record prior to progressing to the next production cycle.

(d) In the past 2 years at least 6 deviations were open beyond the allowed (b) (4) maximum, (b) (4) as required by SOP PDR-QA-0016. Deviations noted include but are not limited to PR # 446003 (open 91.2 days), PR # 452650 (open 86.92 days), PR # 452676 (open 86.88 days), PR # 454454 (open 76.71 days), PR # 467767 open (40.96 days), and PR # 472848 (31.96 days).

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	Seneca D. Toms, Investigator Charanjeet S. Jassal, Investigator	03/20/2015

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OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

(a) During the review of Out of Specifications Investigation Report PR-401269, PR-402709, PR-373458, PR-382184, PR-403760 and PR-379041 it was observed that unknown/extraneous peaks were observed during (b) (4) analysis of samples. In all cases, glassware and/or analyst cross-contamination was determined to be the root cause of the problem. However, the firm made no attempt in (b) (4) identification of the contaminant to ensure that the extraneous peaks were not decomposition byproducts resulting from the product analysis.

(b) Specifically, your firm utilizes procedure PDR-ICP-1721 version 4.0 with an effective date of 1/3/2013 to calibrate your (b) (4) used for product testing. However, the procedure does not challenge (b) (4) or (b) (4) which encompasses the typical range of finished product analysis.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

(a) During the microbiology laboratory tour, it was observed that your (b) (4) incubator bearing instrument number INS-M5714, INS-M5715, INS-M7204 and INS-M7260 missed a (b) (4) check as prescribed in SOP PDR-INS-0029. The corresponding logbook for the above equipment states in part, "assays were not affected." However, your firm failed to initiate an investigation to assess any quality impact on your product.

(b) Aberrant dissolution results for (b) (4) Capsules which failed L1 dissolution criteria were captured in Aberrant /Atypical Data Investigations Report, PR-493108. However, (b) (4) month dissolution assay, (b) (4) month (Part 2) dissolution assay and (b) (4) month dissolution assay all failed L1 specifications but no Aberrant/Atypical Data Investigations Reports were generated for these data. This is in violation of your internal SOP PDR-QA-0003 which states in part, "Aberrant/atypical Data - Any data or result that is inconsistent with expected..."

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OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

(a) Your firm does not have a procedure for logging in and out times for culture stocks and sample used in the Microbiology Lab, which are temperature sensitive.

(b) Your firm did not perform a Performance Qualification (PQ) for the (b) (4) Check Weigher used in manufacturing bearing serial number (b) (4) Furthermore, your firm failed to document scientific rationale to exclude performing a PQ as outlined in SOP PDR-VAL-0020.

OBSERVATION 5

Procedures describing the warehousing of drug products are not followed.

Specifically,

(a) On 3/18/15 while conducting a walkthrough of the Warehouse area, we observed a pallet containing (b) (4) (b) (4) lot numbers (b) (4) marked "Released" in location D3. The count, location and status of the observed product did not the match count, location and status in your validated (b) (4) system. Additionally, the product was expired, but was not marked as such.

(b) Your firm uses a non-proceduralized informal spreadsheet to keep inventory of all incoming materials prior to data entry into your validated software system (b) (4) as described in SOP PDR-MMG-0016, and SOP PDR-MMG-0002.

OBSERVATION 6

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

Specifically,

During the review of Deviation Reports PR-486029, PR-462643 and PR-464908 it was observed that stability testing was performed outside the stability testing date range as prescribed in SOP PDR-LAB-0058. In all deviation reports your firm failed to mention a non-proceduralized practice that tracks stability sample due dates using an informal Excel spreadsheet as a potential root cause of the deviation.

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