DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	06/01/2009 - 06/30/2009* FEI NUMBER 1450114

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kimberly J. Wasserkrug, Executive Director, Quality and Quality Control

FIRM NAME	STREET ADDRESS
Akorn, Inc.	1222 W Grand Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Decatur, IL 62522-1412	Drug Manufacturer/Packaging Operation

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

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, Akorn, Inc. Quality Control Unit failed to perform thorough investigations to include but not limited to the following:

1. Akorn's Quality Control Unit failed to implement an investigation to globally address all out-of-specifications (OOS) Foreign Matter rejects for Fluorescein Injection, USP, (AK-Fluor) 100mg/mL, 5 mL vial, Product Code 5010.

   A. AK Fluor has experienced approximately 16 Non-Laboratory OOS investigations initiated for finished product which resulted in foreign matter reject limit of a maximum allowable percentage rate of b(4) for Year 2007; approximately 13 Non-Laboratory OOS investigations initiated for finished product which resulted in foreign matter reject limit of a maximum allowable percentage rate of b(4) latter revised to b(4) for Year 2008, and approximately 4 Non-Laboratory OOS investigations initiated for finished product which resulted in foreign matter reject limit of a maximum allowable percentage rate of (b) (4) % for Year 2009. During the previous inspection date completed 08/17/2007, it was also noted as a corrective action, Akorn Inc. committed to changing the container-closure system, which was identified as a "probable root cause", for AK-Fluor, however. As of 02/2009 Akorn has changed from (b) (4) to (b) (4) vial. The new vial is currently in the validation stage. However, as of today the new vials have not been verified to identify the actual root causes of the rejects. As a result, Akorn currently is still experiencing foreign matter rejects in AK-Fluor and has not performed a global investigation to address the on-going foreign matter rejects. Also Akorn initiated numerous foreign matter Non-Laboratory OOS investigations to identify "probable root

cause" as the (b) (4) in the stoppers. Akorn changed to stoppers with reduced (b) (4) levels. However, Akorn has still experienced foreign matter rejects after changing of the stoppers. Currently, there is no global investigation complied to track and trend numerous OOS occurrences to address the root cause, corrective actions, preventative actions, conclusion and follow-up of the Foreign Matter rejects. **THIS IS A REPEAT OBSERVATION**

B. Akorn Quality Control Unit has not evaluated numerous OOS for Foreign Matter rejects related to AK Fluor in the Management Reviews and Quality Oversight Meetings.

C. Akorn Quality Control Unit has not evaluated numerous OOS for Foreign Matter rejects related to AK-Fluor as required by written procedure, "Technical Review Board", No. QA147. The board has not performed monthly meeting to include tracking to trend increasing amount of foreign matter rejects.

2. The investigations for Fluorescein Injection, USP, (AK-Fluor) 100mg/mL, 5 mL vial, Code 5010, are not thoroughly investigated for foreign matter that is identified by (b) (4) automated Inspection Machine. Since the last inspection in 8/07, 46 of 73 non-laboratory OOS investigations for this product were for foreign matter rejects or approximately 63% of total non-laboratory OOS's for this product. In 2007, the finished product had a foreign matter reject limit of a maximum allowable percentage rate of (b) %. In 2008, the foreign matter reject limit was increased to a maximum of (b) (4) %. However, the following investigations do not adequately determine the root cause or source of the foreign matter in the finished product that was identified by the automated inspection equipment. The following investigations state that the automated inspection equipment can effectively remove vials with foreign matter (particulates), but there is no documentation on the definitive source of the foreign matter, other batches that may be affected, product impact, the effect on the end-user, and what the firm intends on doing to prevent the occurrence of the foreign matter in future batches.

To include but not limited to the following investigations foreign matter:

A. Non-Laboratory Out of Specification 07-21-00535 for AK-Fluor batch (b) (4) was out of specification on 10-19-07 for the foreign matter reject limit. This batch had a foreign matter reject rate of 2% and the maximum allowable percentage was (b) %. The root cause)

of the high foreign matter reject limit was documented as an increased sensitivity of the automated inspection process on the (b) (4) automated machine. The 92 foreign matter rejects that were rejected by the (b) (4) automated equipment were identified as white particles (80), dark particles (8), and glass particles (4). The investigation does not address the source of the foreign matter in the finished product that can be clearly identified by the (b) (4) automated equipment.

B. Non-Laboratory Out of Specification 07-21-00570 for AK-Fluor batch (b) (4) was out of specification on 11-19-07 for the foreign matter reject limit. This batch had a foreign matter reject rate of 22% and the maximum allowable percentage was (b) %. The root cause of the high foreign matter reject limit was documented as an increased sensitivity of the automated inspection process on the (b) (4) automated machine. The 900 foreign matter rejects that were rejected by the (b) (4) automated equipment were identified as white particles (767) and dark particles. The investigation does not address the source of the foreign matter in the finished product that can be clearly identified by the (b) (4) automated equipment.

C. Non-Laboratory Out of Specification 08-21-00236 for AK-Fluor batch (b) (4) was out of specification on 6-18-08 for the foreign matter reject limit. This batch had a foreign matter reject rate of 20% and the maximum allowable percentage was (b) %. The 730 foreign matter rejects that were rejected by the (b) (4) automated equipment were identified as white particles (407), dark particles (113), glass particles (1), and vials without particles (323). The root cause of the high foreign matter reject limit was documented as unknown at that time. The investigation includes a preventive action statement that said the firm is looking to replace the (b) (4) stopper with a (b) (4) (b) (4) stopper. The investigation does not include documentation about how the (b) (4) content of the stopper was discovered as a possible cause of the foreign matter.

D. Non-Laboratory Out of Specification 08-21-00251 for AK-Fluor batch (b) (4) was out of specification on 6-25-08 for the foreign matter reject limit. This batch had a foreign matter reject rate of 35% and the maximum allowable percentage was (b) %. The 315 foreign matter rejects that were rejected by the (b) (4) automated equipment were identified as white particles (159), dark particles (1), lowfills (10), and vials without particles (145). The investigation also stated that the majority of the rejects had the appearance of (b) (4) that would quickly dissipate. It also stated that the (b) (4)

stoppers are being evaluated for replacement with a non-(b) (4) stopper. The root cause of the high foreign matter reject limit was documented as an increased sensitivity of the automated inspection process on the (b) (4) automated machine. An attachment to the OOS lists these two probable causes for the higher number of rejects.

3. The following Out-of-Specification (OOS) Investigations were not thoroughly investigated:

   A. OOS Investigation No. 07-1-5-006, Labetalol Hydrochloride Injection 546-51557, identified an investigation as part of process validation and batch release due to end of filtration assay test point was indicated as OOS at 105%. The specification for the test point is (b) (4) to (b) (4) %. The lot was OOS excursion occurred dated 05/25/2007, however, the OOS investigation was not discovered until dated 07/12/2007, approximately 1 ½ month later. The investigation included a statement, "Note: This OOS was not issued when the excursion occurred due to a misunderstanding by the analyst on process validation requirement. The analysts were reminded that all OOS results occurring during process validation require a formal investigation." The analyst did not follow written procedure to initial an investigation for OOS occurrences. Akorn does not have any training records stating that the analysts received training related to this investigation. The investigation indicated that the root cause of OOS result was not related to analytical cause. Akorn did not perform any Corrective Action and/or Preventative Action for the OOS result.

   B. OOS Investigation No. 07-1-5-007, Bal-in-Oil Injection 583-81397, identified an investigation as part of process validation and batch release due to end of filtration assay test point was indicated as OOS at 4.4%. The specification for the test point is (b) (4) to (b) (4) %. The investigation stated, "sampling handling was determined to be the probable root cause. This root cause was neither confirmed nor discredited". The investigation also indicated that the root cause of OOS result was not related to analytical cause. Akorn did not perform any Corrective Action and/or Preventative Action for the OOS result.

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OBSERVATION 2

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

Specifically,

1. Akorn amended the Foreign Matter specifications for drug product Fluorescein Injection, USP, (AK-Fluor) 100mg/mL, 5 mL vial, Product Code 5010, to increase the foreign matter rejection specification from a maximum allowable percentage rate from (b)(4)% to (b)(4)%. The percentage rates for (b)(4)% and (b)(4)% were based on historical data; no scientific justification was noted for each percentage rate. For 2008, approximately 8 additional Non-Laboratory Out-of-Specification (OOS) investigations were initiated as a result of Foreign Matter rejects for AK-Fluor. The amended rate of (b)(4)% did not identify the root cause in order to prevent reoccurrences of foreign matter rejects. To include but not limited to the following Non-Laboratory OOS investigations were also noted for foreign matter:

- Lot (b)(4), Non-Lab OOS 08-21-00219; reject rate 15.0%
- Lot , Non-Lab OOS 08-21-00236; reject rate 18.8%
- Lot , Non-Lab OOS 08-21-00245; reject rate 13.7%
- Lot , Non-Lab OOS 08-21-00251; reject rate 29.3%
- Lot , Non-Lab OOS 08-21-00258; reject rate 20.0%
- Lot , Non-Lab OOS 08-21-00269; reject rate 15.7%
- Lot , Non-Lab OOS 08-21-00313; reject rate 29.3%
- Lot , Non-Lab OOS 08-21-00320; reject rate 13.8%

Currently, for Year 2009 approximately 4 Non-Laboratory OOS investigations were also noted for foreign matter:

- Lot (b)(4), Non-Lab OOS 09-21-00082; reject rate 29.0%
- Lot , Non-Lab OOS 09-21-00088; reject rate 27.0%
- Lot , Non-Lab OOS 09-21-00093; reject rate 21.0%

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EMPLOYEE(S) SIGNATURE	DATE ISSUED
Debra I. Love, Investigator Lequita M. Mayhew, Investigator	06/30/2009

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- Lot (b) (4), Non-Lab OOS 09-21-00141; reject rate 28.0%

2. Akorn has not implemented a written procedure detailing the specifications for foreign matter rejects to determine the types of rejects present. The personnel manually examine (b) (4) % of the total rejected vials from the (b) (4) Inspection Machine process. There is no written procedure detailing to examine (b) (4) of rejected vials. The examination of (b) (4) was based on historic data and not scientific justification.

3. Akorn Inc. failed to validate each individual media lot of Tryptic Soy Agar (TSA) rodac plates used to challenge the performance growth promotion of positive control standards used to identify Clostridium (C.) *sporogenes*, a pathogenic anaerobic organism reportedly associated in gangrenous infections. It has been identified since approximately 11/2003 to approximately 06/2008 the microbiology department did not utilize the appropriate media for environmental monitoring. TSA with lecithin and polysorbate 80 rodac plates vendor (b) (4) did not support C. *sporogenes* growth. It was noted that vendor's Certificate of Analysis of rodac plates did not include C. *sporogenes*. The rodac plates are used to monitor anaerobes in Level I environments of areas C, K, P, AH & AJ. As a result, of the media used which did not support the growth of C. *sporogenes*, Akorn can not assure that monitoring of areas utilized for manufacturing of sterile drug products do not include contamination of Clostridium *sporogenes*.

   A. For Year 2008 Akorn purchased and used for environmental monitoring approximately (b) (4) lots of TSA, which did not support growth of C. *sporogenes*; Year 2007 Akorn approximately (b) (4) lots of TSA; Year 2006 approximately (b) (4) lots of TSA; Year 2005 approximately (b) (4) lots of TSA; Year 2004 approximately (b) (4) lots of TSA; Year 2003 approximately (b) (4) lots of TSA. In total Akorn purchased and used approximately (b) (4) lots which did not support growth of C. *sporogenes*.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

1. The validation protocol for Media Fill Validation for the 5mL & 100mL vials in Rooms AH/AJ

(Lyo Area) utilizing Lyophilize(b) (4) listed key issues under the study design section that were not followed in the execution of the protocol. Therefore, the protocol requirements for the validation were not met. The following are the examples of requirements that were not followed in the execution of the protocol.

a. The fill volume requirement for the 5mL vial was (b) (4). The fill volume was only(b) (4) or(b) % for the(b) (4) mL vial.
b. The protocol included a fill speed rate of(b) vpm (vials per minute) for the(b) (4) mL vial. The fill speed rate for the(b) mL vial was run at a rate of(b) (4)
c. The protocol stated that duration of post-sterilization hold time for the pre-sterilized parts and components was to be NLT(b) (4) hours. The hold time was less than(b) (4) hours for the majority of the hold times.
d. The protocol stated that chamber for the lyophilizer must be held under slight vacuum conditions to simulate the process. The slight vacuum conditions were not created during the hold time when the media filled vials were in the lyophilizer chamber.

2. Failure to thoroughly investigate Media Fill Batch(b) (4), Code(b) (4), 100mL vials, performed in filling area AH and lyophilization in room AJ on 7-28-08 when it was invalidated. The batch was invalidated because batch(b) (4) failed to support the growth promotion test for Micrococcus luteus at the(b) (4) incubation temperature for Tray #(b) (4)

3. Failure to thoroughly investigate Media Fill Batch(b) (4), Code(b) (4), 100mL vials, performed in filling Area AH and lyophilization in room AJ on 9/30/08 when it was aborted. Batch(b) (4) (b) (4) was aborted because of a malfunction of the surge vessel.

4. Failure to thoroughly investigate Media Fill Batch(b) (4), Code(b) (4), performed on 10-30-08 in Tank(b) (4) used for bulk sterilization. The batch was aborted due to a hose that came off the adapter during the filtration of the bulk solution.

5. Lack of assurance that the microbiological growth media does in fact contact all of the interior surfaces of the LDPE bottles as well as the dispensing tip for the aseptic media fill process for ophthalmic finished products. The white color LDPE bottles does not allow for visually observing microbial growth that may be present in the inside of the finished product container. The dispenser tips are also made of opaque material which also does not allow for visually observing microbial growth that may be present. **THIS IS A REPEAT OBSERVATION**

6. Failure of the have an adequate preventive action for the storage of integral rejects (intervention integral rejects) for Media Fill Batch(b) (4) for Code(b) (4), 100mL vials, performed in filling Area AH and lyophilization in room AJ on 1/23-24/08. After filling, batch(b) (4) had 75 integral rejects (intervention integral rejects). The integral rejects were accidently disposed of by a production employee along with non-integral rejects while awaiting transfer to the incubator at another facility. This media fill was used to support the validation of filling area AH and Lyophilizer's(b) (4)

7. The initial review of the media fill batch records did not identify unauthorized pen amendment changes made by a production employee for the following Media Fill Batches:(b) (4) (b) (4), and(b) (4). A production employee crossed out the non-braided tubing, part number(b) (4), listed in the batch record and made handwritten changes using a pen for the purpose of using a similar tubing, part number(b) (4), without Quality Assurance approval at the time it was actually used in the media fills. This tubing is not listed in the master batch record for Media Fill Code(b) (4) for Xylazine, Code(b) (4) for Media Fills using 5 mL vials in filling area AH, Code(b) (4) for Sarapin Injection, and Code(b) for Orphenadrine Citrate Injection USP. The pen amendments were not identified until the final review by a second QA official.

8. Specifically, the validation protocol, V1904-08-00, entitled Process Simulation (Media Fill)Media Fill Validation for the 5mL & 100mL vials in Rooms AH/AJ (Lyo Area) utilizing Lyophilizer (b) (4) included specific procedural requirements referenced in SOP AA204, the Medial Fill Process Simulation Program. The protocol was approved by Quality Assurance even though some of the necessary requirements referenced in SOP AA204 were not correctly included in the original or executed protocol. Some requirements were also listed in the master batch record for the media fill and some were not referenced in the batch record. Because the requirements were incorrectly included in the original and executed protocol, several deviations occurred during the validation. The following are some of the deviations listed in the summary report for the validation.

   a. The fill volume requirement for the 5mL vial was(b) (4) mL or(b) (4)%. The fill volume was only(b) g or(b) (4)% for the 5 mL vial. The root cause of the protocol deviation was that the protocol was different than what was required in the batch record.
   b. The fill speed for the 100mL vial was run at a fill rate of(b) (4) vpm (vial per minute). The

protocol included a fill speed rate of (b)(4) vpm. The root cause of the protocol deviation was that the protocol was different that what was required in the batch record.

c. The protocol stated that chamber for the lyophilizer must be held under slight vacuum conditions to simulate the process. The slight vacuum conditions were not created during the hold time when the media filled vials were in the lyophilizer chamber.

OBSERVATION 4

Written procedures are not drafted, reviewed and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

Specifically, Ofloxacin Opthalmic Solution, USP, 0.3% failed to include detailed instructions and/or an investigation during validation of three batchs related to changes in equipment.

A. Product Code 5132, Lot No (b)(4), initially started with (b)(4) mixer attached to Tank (b)(4), however, during the addition of Ofloxacin, USP at (b)(4), it was noted that the (b)(4) mixer did not disperse the Ofloxacin, USP powder into the solution. A (b)(4) (b)(4) mixer (b)(4) was installed and used for formulation. Akorn did not initiate an investigation detailing the change to include new equipment. A very brief summary was noted in the comment section; however, the comments did not identify a root cause for new equipment.

B. Product Code 5132, Lot No. (b)(4):

- During manufacture of validation batch, the Quality Control Unit failed to implement an investigation or detailed information related to the change from (b)(4) mixer to (b)(4) mixer that was identified in manufacture of 1st batch Lot No. (b)(4) at Step (b)(4). Akorn did not initiate an investigation detailing the change to include new equipment. A very brief summary was also noted in the comment section.

- The production staff utilized the (b)(4) mixer at Step (b)(4). During manufacture of 1st batch Lot No. (b)(4) it was instructed to discontinue use of the (b)(4) mixer for future manufacture; however, the staff continued use of the mixer. The Master Batch Record and Process Validation Protocol

Ofloxacin Opthalmic Solution, USP, 0.3%, Protocol No. P2615-08-00, did not include instructions for an additional remix at Step(b) (4). An investigation was not initiated to identify the need for utilizing the discontinued(b) (4) mixer and also an additional re-mixing procedure.

C. Product Code 5133, Lot No(b) (4)

- During manufacture of validation batch, the Quality Control Unit failed to implement an investigation or detailed information related to the change from (b) (4) mixer to(b) (4) mixer that was identified in manufacture of 1st batch Lot No(b) (4) at Step(b) (4). Akorn did not initiate an investigation detailing the change to include new equipment. A very brief summary was also noted in the comment section.

- The production staff utilized the (b) (4) mixer at Step(b) (4). During manufacture of 1st batch Lot No.(b) (4) it was instructed to discontinue use of the(b) (4) mixer for future manufacture; however, the staff continued use of the mixer. The Master Batch Record and Process Validation Protocol Ofloxacin Opthalmic Solution, USP, 0.3%, Protocol No. P2615-08-00, did not include instructions for an additional remix at Step(b) (4). An investigation was not initiated to identify the need for utilizing the discontinued(b) (4) mixer and also an additional re-mixing procedure.

OBSERVATION 5

Routine checking of automatic equipment is not performed according to a written program designed to assure proper performance.

Specifically, Akorn Inc., Quality Control Unit failed to review, approve, and perform corrective actions to the following:

1. The Quality Control Unit failed to accurately validate the(b) (4) Inspection Machine for

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Fluorescein Injection, USP, (AK-Fluor) 100mg/mL, 5mL vial, Product Code 5010, to detect new type of foreign matter rejects due to a change in (b) (4) stoppers. Akorn did not re-validate (b) (4) (b) (4) Stoppers after the vendor change to a higher (b) (4) level within the stoppers. It was only identified after Akorn experienced numerous Non-Laboratory OOS investigations during AQL inspections for foreign matter rejects. Approximately 16 Foreign Matter rejects for Year 2007 and for Year 2008 approximately 5 Foreign Matter rejects for AK-Fluor, with specification rejection rate over (b) % to include but not limited to the following:

- Lot (b) (4) Non-Lab OOS 07-21-00583; reject rate 24.7%
- Lot Non-Lab OOS 07-21-00580; reject rate 22.6%
- Lot , Non-Lab OOS 07-21-00535; reject rate 1.9%
- Lot , Non-Lab OOS 07-21-00537; reject rate 3.4%
- Lot , Non-Lab OOS 07-21-00541; reject rate 9.8%
- Lot , Non-Lab OOS 07-21-00547; reject rate 13.0%
- Lot , Non-Lab OOS 07-21-00554; reject rate 12.2%
- Lot , Non-Lab OOS 07-21-00567; reject rate 15.2%
- Lot , Non-Lab OOS 07-21-00570; reject rate 21.9%
- Lot , Non-Lab OOS 07-21-00588; reject rate 21.0%
- Lot , Non-Lab OOS 07-21-00565; reject rate 9.6%
- Lot , Non-Lab OOS 07-21-00600; reject rate 9.1%
- Lot (b) (4) , Non-Lab OOS 07-21-00615; reject rate 15.0%
- Lot , Non-Lab OOS 07-21-00618; reject rate 14.4%
- Lot , Non-Lab OOS 07-21-00630; reject rate 12.1%
- Lot , Non-Lab OOS 07-04-00641; reject rate 17.8%
- Lot , Non-Lab OOS 08-21-00002; reject rate 14.6%
- Lot , Non-Lab OOS 07-28-00011; reject rate 28.5% for batch to include initial inspection and re-inspection rate.
- Lot (b) (4) , Non-Lab OOS 08-21-00059; reject rate 15.8%
- Lot , Non-Lab OOS 08-21-00068; reject rate 18.9%
- Lot , Non-Lab OOS 08-21-00131; reject rate 13.8%
- Lot , Non-Lab OOS 08-21-00144; reject rate 11.7%

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Debra I. Love, Investigator Lequita M. Mayhew, Investigator DLL DM	06/30/2009

2. The written procedure SOP ML157, Identification of Microbial Isolates, does not include instructions for the user to evaluate the power spikes (surges) when a card is in the reader on the (b) (4) Identification System. The power spikes (surges) could affect the reading of the card inside the (b) (4) which identifies the microorganism. Cards that are not read (meaning there are no identification results) could be related to the power spikes (surges). The performance of the (b) (4) is evaluated by the results from the readings on the cards.

   - For example, on 2/5/08 at 1743, the message recorded on the (b) (4) Error Log said that "the reader experienced a power failure". There is a note that one card was in (b) (4) at time of power failure. No ID, identification, will be repeated. The results from this reading were not within the acceptable range of the database for microorganisms within the (b) (4) (b) (4) and the test was repeated. But, Management said the ability of the card to be read or not to be read by the equipment could be related to the power spike (surge). There is no documentation of an evaluation of the performance of the (b) (4) when the card is not read due to a power spike (surge).

OBSERVATION 6

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

Specifically,

1. The written procedure, AA204 Media Fill Process Simulation, does not adequately describe the instructions for the aborting and invalidating of media fill batches. For example,
   a. Media Fill Batch (b) (4), Code 7002, 100mL vials, performed in filling area AH and lyophilization in room AJ on 7-28-08 when it was invalidated after growth promotion acceptance criteria were not met. The instructions in the written procedure do not describe when a media fill batch is invalidated.
   b. Media Fill Batch (b) (4), Code 7002, 100mL vials, performed in filling Area AH and lyophilization in room AJ on 9/30/08 when it was aborted because of a malfunction of the surge vessel. The instructions in the written procedure do not describe when a media fill batch is aborted.

2. There is no written procedure that describes the storage conditions and storage location of integral rejects (intervention rejects) after the media fill is completed at one facility before they are transferred to another facility for incubation. For example,

a. Media Fill Batch (b) (4) for Code 7002, 100mL vials, performed in filling Area AH and lyophilization in room AJ on 1/23-24/08 had 75 integral rejects (intervention integral rejects). The integral rejects were accidently disposed of by a production employee along with non-integral rejects while awaiting transfer to the incubator at another facility.

3. There is no written procedure that describes for the requirement for Quality Assurance to approve handwritten changes (pen amendment changes) to the batch records by production personnel before they are done. For example, a production employee was allowed to cross out the non-braided tubing, part number (b) (4), listed in the media fill batch record and to make handwritten changes using a pen for the purpose of using a similar tubing, part number ASTP - 16F, without Quality Assurance approval at the time it was actually used in the media fills. Pen amendment changes were made to the Media Fill Batches 61268, 61278, 61188, 61178, 61378, and 61058.

4. The written procedure, "Batch Record Review: Product Release/Closeout & Media Review/Closeout", No. QA101, does not adequately describe the instructions for the aborting manufacturing batches. For example,
   a. Lot 21039, Product Code 5010, 100mg/mL, 5mL vials, performed in filling area K on 04/27/2009 was aborted. The batch record does not include any information for aborting the lot. No investigation was included with the batch record.
   b. Lot 91208, Product Code 5010, 100mg/mL, 5mL vials, performed in filling Area K on 09/09/2008. The batch record does not include a thorough investigation detailing abortion of the lot.

OBSERVATION 7

Failure to reject any lot of components, drug product containers, and closures that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically, not all components met the acceptance criteria for incoming sampling, inspections testing and release.

A. According to written procedure, "Sampling, Inspection and Release of Incoming (b) (4) Components, No. WQ114, dated 11/14/2007, specifications for Level 1 major defects (b) (4) % AQL was not met to include but not limited for the following:

- Glass Dropper Assembly, Blister Packed, Sterile (b) (4), Manufacturer Lot No. (b) (4) QA released for use dated 02/29/2008, did not meet specification not to exceed (b) (4) defects for sampling size (b) (4). The Inner Thread Diameter measurements indicated 7 defective caps (remeasurements). Specifications measurement (b) (4) mm to (b) (4) out-of-specification results were: Cap No. 17-10.80 mm; No. 22-10.80 mm; No. 25-10.79 mm; No. 29-10.49; No. 73-10.79; No. 101-10.56; and No. 223-11.92.

- Glass Dropper Assembly, Blister Packed, Sterile (b) (4), Manufacturer Lot No. (b) (4) QA released for use dated 10/23/2008, did not meet specification not to exceed 2 defects for sampling size (b) (4) The Inner Thread Diameter measurements indicated (b) (4) defective caps (remeasurements). Specifications measurement (b) (4) out-of-specification results were: Cap No. 34-10.04 mm; No. 43-10.63 mm; No. 46-10.73 mm; No. 77-11.50; No. 98-10.07; and No. 192-10.64.

- Glass Dropper Assembly, Blister Packed, Sterile (b) (4), Manufacturer Lot No. (b) (4) QA released for use dated 10/23/2008, did not meet specification not to exceed (b) (4) defects for sampling size (b) (4) The Blister width measurements indicated (b) (4) defective blisters (remeasurements). Specifications measurement 39.39 mm to 41.45 (measured at width point); out-of-specification results were: Blister No. 34-39.11 mm; No. 50-39.22 mm; No. 116-39.25 mm; and No. 154-39.24.

B. According to written procedure, "Sampling, Inspection and Release of Incoming Closures", No. WQ103, dated 05/23/2008, specifications for Level 1 major defects (b) (4)% AQL was not met to include but not limited for the following:

- (b) (4) (b) (4) (b) (4) Stoppers, Manufacturer Lot No. (b) (4), Part No. (b) (4), QA released for use dated 04/15/2009, did not meet specification not to exceed (b) (4) defects for sampling size (b) (4) The Height measurements indicated (b) (4) defective heights (remeasurements). Specifications measurement (b) (4) inches to (b) (4) inches; out-of-specification results were: Measurement No. 54-0.3790 inches; No. 72-0.4165 inches; No. 159-0.3800 inches; and No. 287-0.3835 inches.

- (b) (4) (b) (4) (b) (4) Stoppers, Manufacturer Lot No. (b) (4), Part No.

(b) (4), QA released for use dated 04/15/2009, did not meet specification not to exceed(b) defects for sampling size(b). The Height measurements indicated (b defective heights)(remeasurements). Specifications measurement(4)(b) (4) inches to(b) (4) inches; out-of-specification results were: Measurement No. 73-0.2510 inches; No. 219-0.2510 inches; No. 228-0.2530 inches; No. 265-0.2525 inches; No. 279-0.2505 inches; and No. 301-0.2520 inches.

C. The following written procedures are not standardized for sampling for normal inspections according to(b) (4): "Sampling, Inspection and Release of Incoming(b) (4) Components", No. WQ114, dated 11/14/2007; Sampling, Inspection and Release of Incoming Closures", No. WQ103, dated 05/08/2007; Sampling, Inspection and Release of Incoming Labeling Material", No. WQ105, dated 04/17/2008; Sampling, Inspection and Disposition of Incoming Caps", No. WQ113, dated 11/14/2007. Akorn Inc., written procedures indicates that the specifications are reflective of ANSI, however, the aforementioned procedures are not indicative of ANSI specifications for (b) (4) to include major defects and minor defects.

D. Akorn Inc, QA Technicians are not adequately trained to perform incoming specifications utilizing the Calipers for measurement. The operators can not distinguish between operator error and/or out-of-specifications for incoming components. Numerous out-of-specifications were observed to include but not limited to the following lots:

- Glass Dropper Assembly, Blister Packed, Sterile '(b) (4)', Manufacturer Lot No.(b) (4), QA released for use dated 02/29/2008.
- Glass Dropper Assembly, Blister Packed, Sterile '(b) (4)', Manufacturer Lot No. Glass Dropper Assembly, Blister Packed, Sterile '(b) (4)', Manufacturer Lot No.(b) (4), QA released for use dated 10/23/2008.
- Glass Dropper Assembly, Blister Packed, Sterile '(b) (4)', Manufacturer Lot No. Glass Dropper Assembly, Blister Packed, Sterile '(b) (4)', Manufacturer Lot No(b) (4), QA released for use dated 10/23/2008.
- (b) (4) Stoppers, Manufacturer Lot No., Part No.(b) (4), QA released for use dated 04/15/2009.
- (b) (4) Stoppers, Manufacturer Lot No. Part No. QA released for use dated 04/15/2009.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kimberly J. Wasserkrug, Executive Director, Quality and Quality Control

FIRM NAME	STREET ADDRESS
Akorn, Inc.	1222 W Grand Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
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E. The following written procedures," Sampling, Inspection and Release of Incoming (b) (4) Components", No. WQ114, dated 11/14/2007; Sampling, Inspection and Disposition of Incoming Glassware", No. WQ101, dated 11/14/2007; Sampling, Inspection and Release of Incoming Closures", No. WQ103, dated 05/08/2007; Sampling, Inspection and Release of Incoming Labeling Material", No. WQ105, dated 04/17/2008; Sampling, Inspection and Disposition of Incoming Caps", No. WQ113, dated 11/14/2007 does not provide adequate instructions for measurements of incoming components. The QA Technicians routinely perform re-measurements of out-of-specifications components and also do not initiate investigations when it has been determined operator error as a cause of the out-of-specifications.

OBSERVATION 8

Written procedures are not established and followed for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product.

Specifically, written procedure, "Annual Product Review", No. QA119, effective date 07/10/2006, does not provide provisions to accurately determine the need for changes in drug product specifications, manufacturing or control procedures globally to include but not limited to the following drug product and all of Akorn's drug products:

Annual Product Review (APR) Report, Fluorescein Injection, USP, (AK-Fluor)100mg/mL, 5 mL vial, Product Code 5010, dated 09/23/2008, doesn't accurately represent the following:

1. APR did not accurately detail out-of-specifications (OOS) for the following:

   A. Approximately a total of 29 foreign matter Non-laboratory OOS investigations were initiated for Year 2007 and 2008, which resulted to revise foreign matter reject limit of a maximum allowable percentage rate from (b) (4) % to foreign matter reject limit of a maximum allowable percentage rate of (b) (4) %. However, the change in specification did not resolve the foreign matter occurrences. The APR doesn't detail the need to determine changes in drug product specifications and/or manufacturing operations. The APR identifies the foreign matter initiated Non-Laboratory OOS as "inspection" instead of

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the term "foreign matter".

B. Approximately a total of 9 non-viable particulates Non-laboratory OOS investigations were initiated for Year 2007 and 2008. The APR doesn't include detail information related to the investigations.

C. Approximately a total of 5 AQL inspections reject which was performed and noted after excursions of the non-viable particulates. The APR doesn't detail the need to determine changes in drug product specifications and/or manufacturing operations. Non-laboratory OOS investigations were initiated for Year 2007 and 2008. The APR doesn't include detail information related to the initial excursions and the subsequent AQL rejects to include the investigations.

2. Bioburden Level I and II, Room pressure, Particulates Level I, II, and III, Pre-final filter bioburden sections do not represent actual occurrences of out-of-specifications (OOS) for each lot manufactured of AK-Fluor. The results are averaged; however, the averages did not include noted OOS. For examples:

   - Year 2007, deviation section identified six non-viable particulates OOS.
   - Year 2008, deviation section identified 23 non-viable particulates OOS.

3. The AK-Fluor APR Report doesn't identify detailed information representative of actual manufacturing of drug products to include but not limited the following:

   A. Initial Report

      - Product Summary doesn't identified the lot numbers/and or identifying information for lots manufactured, aborted, rejects, released and deviations, OOS reports other detailed information to summary the production.

- Raw Materials and Components section indicates, "The stopper was changed to a reduced level of (b) (4) in January 2008, however, the detail information is not include to address the reason and/or root cause which resulted for the change in components.

- Recommendations section indicates, "Revise foreign matter reject limit based on current (b) (4) settings, however, it does include pertinent information to state numerous OOS resulted to drive the change for limit. The section doesn't include investigation reports and other pertinent information.

B. AK-Fluor 10% (Fluorescein Injection USP, 100 mg/mL Vial, 5mL Vial), Product Code 5010, Lot No. (b) (4) was rejected.

- The Product Summary section or any other section of the APR doesn't provide detail information related to the rejected lot. The lot was rejected due to "Probable root cause is variation in (b) (4) content on stoppers". During AQL sampling inspection and re-inspection of Loads A and B resulted in unacceptable reject rates, indicated due to detection of visual foreign matter in solution. The APR doesn't include information detailing whether or not an investigation was performed to include the root cause, corrective actions and preventative actions.

- Tables noting lot information indicates "NA" for the rejected lot. However, the information is Applicable in order to determine the need for changes in drug product specifications, manufacturing or control procedures.

- Spreadsheets for Non-Lab Investigations for Year 2007 and Year 2008 included with the APR doesn't not provide any information for the rejected lot.

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OBSERVATION 9

Batch production and control records do not include the results of any investigation made into any unexplained discrepancy, whether or not the batch of drug product had already been distributed.

Specifically,

Cited Previous Inspection close-out dated 8/17/07: Akorn's Inc., Non-Laboratory Out of Specification Investigations and Health Hazard Evaluations performed in response to two lots of Fluress (Fluorescein Sodium 2/5 mg/mL / Benoxinate HCL, 4.0 mg/mL, Ophthalmic Solution, USP), a non-approved product, failing to meet Akorn particulate matter specifications.

1. Non-Laboratory Out-of-Specification (OOS) 07-10-00214 was issued by QA on 4/5/07 in response to Fluress lot (b) (4) failing to meet Akorn's particulate matter specification at the (b) (4) month stability test point. The root cause of the failure was attributed to "...an inadvertent revision to add particulate testing to the specification and stability test specs..." The non-laboratory OOS investigation did not determine the source, type or cause of the particulate matter found. The non-laboratory OOS was signed as approved by quality assurance on 5/31/07.

2. Currently, Akorn Corrective Action included removing particulate matter specification from written procedures; however, Akorn has failed to follow-up to identify and to monitor Fluress manufactured subsequent to the previous FDA inspection.

3. As part of the Corrective Action Akorn, changed the previous used cap liners to Mylar cap liners; however, it was noted that the Mylar cap liners, currently contains higher than desired particulate matter. Akorn has not developed any specifications for particulate matter for the new cap liners. Akorn has not completed evaluation of the cap liner. Akorn has failed to implement Corrective Actions.

THIS IS A REPEAT OBSERVATION

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OBSERVATION 10

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

On 6/2/09, we observed a hose connection to the (b) (4) (used to clean equipment) that is used for WFI water touching the floor of the wash area. The hose was then placed in a sink and rinsed off with WFI water and hung on a rack to drain. This hose had two open adaptors, one at each end of the hose. A possibility of contamination entering the adaptor exits because the outside of the hose had contact with the floor and the rinse water contacted the open adaptor at each end of the hose.

OBSERVATION 11

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically,

There is no written procedure to address the rinsing of the hose used to connect the WFI water to the (b) (4) in the washing area. On 6/2/09, we observed a hose connection to the (b) (4) (used to clean equipment) that is used for WFI water touching the floor of the wash area. The hose was then placed in a sink and rinsed off with WFI water and hung on a rack to drain. This hose had two open adaptors, one at each end of the hose. A possibility of contamination entering the adaptor exits because the outside of the hose had contact with the floor and the rinse water contacted the open adaptor at each end of the hose.

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OBSERVATION 12

Complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse drug experiences which are required to be reported to FDA.

Specifically, Akorn's written procedure, "Adverse Drug Experience Reporting", No. RA112, Effective Date 03/19/2007, does not include the new FDA provisions for postmarketing reporting requirements for drug product of Serious Adverse Event Reporting for Non-Prescription Drugs, Chapter VII, SubChapter H, Section 760 of the Food, Drug, and Cosmetic (FD&C) Act which established new adverse event reporting requirements which apply to the manufacturers, packers, and distributors whose names appear on the labels of over-the-counter (OTC) or behind-the-counter (BTC) drugs marketed in the United States.

OBSERVATION 13

Procedures prescribing a system for reprocessing batches to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics are not followed.

Specifically,

1. Akorn Inc, Quality Control Unit failed to assure that study protocol, "Study (b) (4) (b) (4) No. (b) (4) ", Approved by Akorn dated 10/03/2006, to qualify (b) (4) without laminate and with cross-linker was followed. Akorn failed to provide the label vendor (b) (4) with the specification to include print additive of (b) (4) % (b) (4) . During inspections of packaged (b) (4) Lots (b) (4) and (b) (4) it was noted transference of ink from (b) (4) bottle label to inside of pouch during autoclaving. As a result an Out-of-Trend Report #09-15-003 was initiated. Four lots were affected. Lot (b) (4) manufactured dated 09/2008 and Lot (b) (4) manufactured dated 10/2008, which were sterilized and inspected 100% by product and 100% by Quality Assurance. Lots which were legible was released and distributed; lots that were not legible were rejected and destroyed. Lot (b) (4) manufactured 10/2008, were delabeled and relabeled; and Lot (b) (4) manufactured 11/2008, were delabeled and relabeled. Prior to manufacture of the (b) (4) lots the Quality Control Unit did not accurately review Packaging Component Specification No. (b) (4) , effective date 10/31/2006 and provide detailed instructions to the label vendor (b) (4)

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2. Akorn Inc, Quality Control Unit failed to assure that written procedure, "De-Labeling Procedure", Approved by Akorn dated 03/31/2009, for Edrophonium Chloride, USP & atropine sulfate, USP (Enlon Plus) Injection was followed during rework:

   A. "Removing Labels From Ampuls, Vials and Opthalmic Bottles", No. WP104 was not followed for de-labeling vial to add (b) (4) a cleaning agent, into water. (b) (4) was used to soak bottles. Akorn Inc. utilizes during regular operations.

   B. Written procedure, "De-Labeling Procedure", Approved by Akorn dated 03/31/2009, do not include adequate instruction to include interventions and investigation if required. Procedures instruct personnel to monitor the water temperatures hourly, however, numerous occasions of extended time spans greater than (b) (4) between temperatures checks were noted on the Monitoring Potable Water Temperature records.

3. Akorn failed to initiate an investigation for Sufenta (Sufentanil Citrate) Injection Sufentanil Base 0.05mg/mL 5mL Ampul. During review of Batch record Lot No. (b) (4), it was noted that Akorn relabeled the ampules; however, the record does not include an investigation or any other documentation describing the reason for relabeling. The record included Deviation Report No. 08-15-20031, initiated due to the final packaging accountability miscalculated by one ampul. The deviation report was implemented subsequent to delabeling and relabeling. Also the deviation report did not identify the original reason for the delabeling and relabeling process.

*** DATES OF INSPECTION:**
06/01/2009(Mon), 06/02/2009(Tue), 06/03/2009(Wed), 06/04/2009(Thu), 06/05/2009(Fri), 06/08/2009(Mon), 06/09/2009(Tue), 06/10/2009(Wed), 06/11/2009(Thu), 06/12/2009(Fri), 06/15/2009(Mon), 06/16/2009(Tue), 06/17/2009(Wed), 06/19/2009(Fri), 06/29/2009(Mon), 06/30/2009(Tue)

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