DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	05/09/2011 - 05/19/2011* FEI NUMBER 2246848

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Michael P. Stehn, Vice President and General Manager

FIRM NAME	STREET ADDRESS
Akorn Inc.	72 Veronica Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873	Sterile 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

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, there was insufficient data, documentation and evidence to invalidate Out of Specification (OOS) results generated by the Quality Control Laboratory.

A. During the 7/2010 release testing of Paremyd (Hydroxyamphetamine HydroBromide and Tropicamide) Ophthalmic Solution lot 0F40A all four Tropicamide Assay results failed to meet the (b) (4) % release specifications. The results were 94.8, 94.6, 94.8 and 94.7%.

Re-injection of the original solutions confirmed the results. The OOS results were also confirmed when 5 new sample preparations were made. In response to the OOS results, the QC laboratory made changes to the analytical testing procedures. The standard weight was increased, the sample pipeting volume was increased and a newer HPLC system was used. All of the results obtained from the 5 new sample preparations made with the new changes to the testing procedures were within specifications with a mean assay value of 96.2%.

The OOS results were invalidated, even though these initial and retest results were obtained from a validated method that had been in use for over 10 years, the changes to the analytical testing procedures were never validated, and there was no method comparison data to show that the assay method with the changes was superior to the original approved method. There was also no information on whether the OOS initial and retest values were significantly different from the in-specification values obtained after the analytical test procedure was changed. Lot 0F40A was released.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Paul Bellamy, Investigator Paul Bellamy	DATE ISSUED 05/19/2011

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B. During the 6 month Controlled Room Temperature Stability testing of another Paremyd Ophthalmic Solution lot 0B33A in 9/2010 the Tropicamide assay failed to meet the (b) (4) % stability specifications. The results were 94.6 and 94.2%. Again, the same method changes as in observation 1A were made to the analytical testing procedures. All of the results, from the 5 new sample preparations that were made with the method changes, were in-specification with a mean assay value of 96.2%. The stability report only referenced the in-specification values for the lot.

C. During the 4/2011 release testing of AK Poly-Bac Ophthalmic Ointment lot 1D96 the microbial assay result of Polymyxin was OOS when the Day 1 and 2 results were averaged for the b(4) b(4) finished goods sample. The specification was (b) (4) % and the results obtained were 133.6 and 133.2%. To confirm the OOS results, additional samples were sent to a contract testing laboratory (b) (4) for additional testing.

All results from the contract testing laboratory were below 120.0% and these results were averaged with the OOS Akorn results and an in-specification overall average was reported for the lot. Prior to the release of this lot, the Quality investigation did not explain why a contract testing laboratory only needs to be used when OOS results are obtained by Akorn i.e. Samples from lots in which Akorn obtained in-specification data are not routinely sent to the contract testing laboratory for further testing. Also, there was no data to support the accuracy or equivalence of the testing done by Akorn and the contract testing laboratory since the laboratories had Polymyxin assay results that differed by over 10%.

*** DATES OF INSPECTION:**
05/09/2011(Mon), 05/10/2011(Tue), 05/11/2011(Wed), 05/12/2011(Thu), 05/13/2011(Fri), 05/18/2011(Wed), 05/19/2011(Thu)

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