DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	12/4/2017-12/12/2017* FEI NUMBER 3005531475

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Jens-Uwe Rengers, General Manager

FIRM NAME	STREET ADDRESS
Akorn AG	Riethofstrasse 1
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hettlingen, Zurich, 8442Switzerland	Manufacture of finished drug product

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

The accuracy, sensitivity and reproducibility of test methods have not been established and documented.

Specifically, the analytical test methods are not adequately transferred from the validating laboratories to this firm to assure that drug products meet appropriate standards of identity, strength, quality, and purity.

The method transfers are incomplete because forced degradation studies were not performed by the firm's laboratory (receiving laboratory) to establish the specificity of the method under actual conditions of use, accounting for interlaboratory variances such as variances in detectors, instrumentation, and analytical technique. These methods are used as stability-indicating procedures and cannot be considered validated without sufficient testing to ensure that the analyte of interest can be adequately resolved from impurities/degradants formed throughout the lifetime of the product. These methods are used for testing and releasing of in-process and finished products, e.g. (b) (4), (b) (4), (b) (4) gel, (b) (4) gel.

OBSERVATION 2

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EMPLOYEE(S) SIGNATURE
Yasamin Ameri, Chemist/Biologist

X Yasamin Ameri
Chemist/Biologist
Signed By 2001565939
Date Signed 12-12-2017 09:22:42

DATE ISSUED
12/12/2017

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CITY, STATE, ZIP CODE, COUNTRY Hettlingen, Zurich, 8442Switzerland	TYPE ESTABLISHMENT INSPECTED Manufacture of finished drug product

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, qualification for aseptic filling area, room (b) (4) (ISO class A and B), is deficient in that the smoke study failure for the room is not identified and investigated. This room currently is used for filling and packaging of drug products which are commercially distributed.

OBSERVATION 3

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,

1- The efficacy of the (b) (4) system used for sanitization and elimination of contaminants in the aseptic fill room is not evaluated for the hard to reach areas. For example, your room qualification for aseptic fill room (b) (4) which includes the filling machine (b) (4) (ID # A31) did not evaluate the penetration level and efficacy of the (b) (4) inside the filling machine (b) (4).

2- The cleaning and disinfecting procedure does not include detailed cleaning and disinfecting procedure when maintenance is conducted on the filling machine.

OBSERVATION 4

The written stability testing program is not followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Yasamin Ameri, Chemist/Biologist X Yasamin Ameri Chemist/Biologist Signed By 2001565939 Date Signed 12-12-2017 09 22 42	12/12/2017

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Specifically, the stability study protocol requirements are not fully followed. For example the stability study for (b) (4) % is missing examination of samples for "Minimum Fill Average, USP" at 3, 6, 9, and 18 months.

***DATES OF INSPECTION**
12/04/2017(Mon), 12/05/2017(Tue), 12/06/2017(Wed), 12/07/2017(Thu), 12/08/2017(Fri), 12/11/2017(Mon), 12/12/2017(Tue)

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	Yasamin Ameri, Chemist/Biologist	X Yasamin Ameri Chemist/Biologist Signed By 2001565939 Date Signed 12-12-2017 09 22 42	12/12/2017