

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187	DATE(S) OF INSPECTION 4/20/2017-4/26/2017*
	FEI NUMBER 1450114

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan D. Shoemaker , Vice President and General Manager

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

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

Specifically,

On 04/20/2017, I observed particles coming off the conveyor belt that stages previously washed vials for entry into the (b) (4) that feeds filling room (b) (4) and identified this issue to the Vice President of Domestic Sterile Products Quality Assurance. Despite this discussion the firm did not correct the problem before releasing this vial line to continue to manufacture product code 547 Labetalol HCl 5mg/mL (40 mL in 50 mL vial) lot 041417 and subsequently manufacture product code 546 Labetalol HCl 5 mg/mL (20 mL in 20 mL) vial Lot 041227.

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

Room (b) (4) contains the vial washer and the entrance to the (b) (4) that feeds filling room (b) (4). The firm uses a (b) (4) conveyor belt to stage vials for entry into the (b) (4). On 04/20/2017, I observed particles coming off the conveyor belt that stages previously washed vials for entry into the (b) (4). The particles were of the same (b) (4) color as that of the conveyor belt. The particles were too many to count, varying in size, and were accumulating

AMENDMENT 1

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		X Brian D Nicholson Investigator Signed by: Brian Nicholson -S

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at both ends of the staging belt. The following lots of sterile drug products have been manufactured on this filling line between the time of the installation of the conveyor belt in the current configuration and 04/20/17 when I pointed out this issue to firm management.

CODE #	PRODUCT	Lot Number	FILLING DATE	QA RELEASE DATE	UNIT SIZE	BATCH SIZE
5010	AK-FLUOR	11015	1/13/2015	3/6/2015	5ML	(b) (4)
5010	AK-FLUOR	11025	1/16/2015	3/25/2015	5ML	(b) (4)
5010	AK-FLUOR	11245	1/23/2015	3/6/2015	5ML	(b) (4)
5010	AK-FLUOR	11255	1/27/2015	3/27/2015	5ML	(b) (4)
5010	AK-FLUOR	11345	2/2/2015	3/27/2015	5ML	(b) (4)
5010	AK-FLUOR	21155	2/5/2015	4/24/2015	5ML	(b) (4)
518	METHYLENE BLUE	21475	2/20/2015	3/27/2015	10ML	(b) (4)
518	METHYLENE BLUE	21575	2/26/2015	3/27/2015	10ML	(b) (4)
518	METHYLENE BLUE	21735	2/28/2015	3/27/2015	10ML	(b) (4)
5012	AK-FLUOR	31235	3/10/2015	4/24/2015	2ML	(b) (4)
517	METHYLENE BLUE	31215	3/11/2015	4/24/2015	1ML/2ML	(b) (4)
5012	AK-FLUOR	31245	3/12/2015	4/24/2015	2ML	(b) (4)
517	METHYLENE BLUE	31225	3/13/2015	5/4/2015	1ML/2ML	(b) (4)
5012	AK-FLUOR	31255	3/16/2015	4/30/2015	2ML	(b) (4)
518	METHYLENE BLUE	31065	3/17/2015	5/4/2015	10ML	(b) (4)
5010	AK-FLUOR	31475	3/19/2015	5/19/2015	5ML	(b) (4)
5010	AK-FLUOR	31485	3/25/2015	5/26/2015	5ML	(b) (4)
5012	AK-FLUOR	31655	3/26/2015	6/11/2015	2ML	(b) (4)
5010	AK-FLUOR	31625	3/27/2015	6/9/2015	5ML	(b) (4)
5010	AK-FLUOR	31785	4/1/2015	6/10/2015	5ML	(b) (4)
517	METHYLENE BLUE	41185	4/2/2015	6/24/2015	1ML/2ML	(b) (4)
518	METHYLENE BLUE	41325	4/13/2015	6/24/2015	10ML	(b) (4)
5012	AK-FLUOR	61065	6/2/2015	10/29/2015	2ML	(b) (4)
5010	AK-FLUOR	61035	6/3/2015	7/28/2015	5ML	(b) (4)
517	METHYLENE BLUE	61205	6/4/2015	7/6/2015	1ML/2ML	(b) (4)
5010	AK-FLUOR	61095	6/5/2015	7/31/2015	5ML	(b) (4)
518	METHYLENE BLUE	61185	6/9/2015	7/6/2015	10ML	(b) (4)
5012	AK-FLUOR	61375	6/11/2015	12/15/2015	2ML	(b) (4)
5010	AK-FLUOR	61235	6/12/2015	8/10/2015	5ML	(b) (4)
518	METHYLENE BLUE	61425	6/16/2015	7/15/2015	10ML	(b) (4)
5010	AK-FLUOR	61475	6/18/2015	8/31/2015	5ML	(b) (4)
517	METHYLENE BLUE	61495	6/19/2015	7/24/2015	1ML/2ML	(b) (4)
5010	AK-FLUOR	61605	6/22/2015	9/21/2015	5ML	(b) (4)
518	METHYLENE BLUE	61515	6/24/2015	8/5/2015	10ML	(b) (4)

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518	METHYLENE BLUE	61635	6/26/2015	9/4/2015	10ML	(b) (4)
517	METHYLENE BLUE	71065	7/6/2015	8/17/2015	1ML/2ML	
5010	AK FLUOR	71015	7/7/2015	9/23/2015	5ML	
518	METHYLENE BLUE	71035	7/8/2015	9/24/2015	10ML	
5012	AK FLUOR	71135	7/10/2015	1/15/2016	2ML	
518	METHYLENE BLUE	71085	7/14/2015	10/13/2015	10ML	
546	LABETALOL	71145	7/18/2015	8/31/2015	20ML	
5010	AK FLUOR	71155	7/20/2015	10/28/2015	5ML	
517	METHYLENE BLUE	71375	7/22/2015	9/8/2015	1ML/2ML	
518	METHYLENE BLUE	71485	7/31/2015	11/2/2015	10ML	
517	METHYLENE BLUE	81405	8/17/2015	9/11/2015	1ML/2ML	
517	METHYLENE BLUE	81535	8/21/2015	10/6/2015	1ML/2ML	
517	METHYLENE BLUE	81745	8/25/2015	10/14/2015	1ML/2ML	
517	METHYLENE BLUE	81775	9/1/2015	11/9/2015	1ML/2ML	
517	METHYLENE BLUE	91055	9/3/2015	12/3/2015	1ML/2ML	
517	METHYLENE BLUE	91145	9/11/2015	1/21/2016	1ML/2ML	
5010	AK FLUOR	91175	9/14/2015	11/12/2015	5ML	
517	METHYLENE BLUE	91365	9/15/2015	1/26/2016	1ML/2ML	
621	LEVOFLOXACIN	91215	9/22/2015	11/19/2015	30ML	
622	LEVOFLOXACIN	101245	10/2/2015	12/16/2015	20ML	
5010	AK FLUOR	101305	10/14/2015	12/17/2015	5ML	
518	METHYLENE BLUE	111435	11/18/2015	1/29/2016	10ML	
546	LABETALOL	111445	11/24/2015	12/28/2015	20ML	
547	LABETALOL	121315	12/22/2015	2/15/2016	40ML	
5010	AK FLUOR	11036	1/8/2016	2/15/2016	5ML	
5010	AK FLUOR	11046	1/13/2016	4/14/2016	5ML	
5010	AK FLUOR	11326	1/25/2016	3/4/2016	5ML	
546	LABETALOL	21426	2/19/2016	3/18/2016	20ML	
5010	AK FLUOR	21576	2/25/2016	3/23/2016	5ML	
622	LEVOFLOXACIN	31096	3/9/2016	4/13/2016	20ML	
546	LABETALOL	31486	3/22/2016	4/22/2016	20ML	
5010	AK FLUOR	31496	3/23/2016	4/22/2016	5ML	
5010	AK FLUOR	31506	3/28/2016	4/28/2016	5ML	
5010	AK FLUOR	41066	4/11/2016	5/17/2016	5ML	
5010	AK FLUOR	41436	4/19/2016	6/1/2016	5ML	
622	LEVOFLOXACIN	41576	4/29/2016	7/14/2016	20ML	
546	LABETALOL	61396	6/17/2016	11/9/2016	20ML	
5010	AK FLUOR	61606	6/24/2016	11/15/2016	5ML	
517	METHYLENE BLUE	61655	6/25/2016	8/5/2015	1ML/2ML	
5010	AK FLUOR	81386	8/25/2016	2/1/2017	5ML	

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5012	AK FLUOR	81276	8/26/2016	2/7/2017	2ML	(b) (4)
5010	AK FLUOR	81396	8/29/2016	2/1/2017	5ML	(b) (4)
5012	AK FLUOR	81416	8/30/2016	2/20/2017	2ML	(b) (4)
5012	AK FLUOR	81426	9/1/2016	2/7/2017	2ML	(b) (4)
5010	AK FLUOR	91016	9/2/2016	2/7/2017	5ML	(b) (4)
5012	AK FLUOR	91066	9/9/2016	12/16/2016	2ML	(b) (4)
5010	AK-FLUOR	111176	11/8/2016	1/24/2017	5ML	(b) (4)
621	LEVOFLOXACIN	111046	12/1/2016	2/13/2017	30ML	(b) (4)
546	LABETALOL	121146	12/6/2016	2/16/2017	20ML	(b) (4)
5010	AK-FLUOR	121316	12/15/2016	3/10/2017	5ML	(b) (4)
5010	AK-FLUOR	121576	12/29/2016	3/1/2017	5ML	(b) (4)
5010	AK-FLUOR	11057	1/11/2017	3/22/2017	5ML	(b) (4)
547	LABETALOL	21437	2/22/2017	3/28/2017	40ML	(b) (4)

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, the firm has failed to complete or invalidated 33% (b) (4) media fills attempted in Filling Room (b) (4) since it has been converted to an aseptic filling area.

***DATES OF INSPECTION**

4/20/2017(Thu),4/21/2017(Fri),4/24/2017(Mon),4/25/2017(Tue),4/26/2017(Wed)

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