DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION 5/3
550 W. Jackson Blvd. Chicago, IL 60661 (312) 353-5863 (FAX: 312-596-4190)	4/9-20/18, 5/3/18, 5/7-11,16/18
	FEI NUMBER 1450114

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

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

Observation 1

Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes.

Aseptic behavior is described in AA143 Aseptic Technique procedure, revision 32, dated 4.9.18.

A. During the inspection, our investigators observed poor aseptic processing techniques that were previously videotaped at your facility (b) (4) line (aseptic/(b) (4) sterilized) and (b) (4) line (b) (4) sterilized)) as well as during a walk-through inspection of (b) (4) line on 4/9/18.
   1. Operators were seen reaching over open vials during interventions. These vials were not removed from the line. Interventions are not executed using the closest door available. During the review of the video, we observed interventions on the far side of the filling area being executed from the near side of the filling area.
   2. The addition of rubber stoppers is not performed aseptically. The stopper bag is held over the head of the operator and dangled through the (b) (4) The bag touches the inside of the hopper and is shook to empty the stoppers bag. Smoke studies show the operator touching the inside of the hopper with his glove during addition. The outer bag was removed up to 20 minutes prior to addition. The inner bag was handled multiple times during this period.
   3. Operators were seen touching their gowning. In one case the operator touched their lower leg/shoe, then proceeded to touch a stopper bag.
   4. Fallen vials were not removed and instead replaced onto the line.

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5. Spraying of the stopper bags before loading is not always performed.
6. The full surface of the door exposed to the Class 10,000 area is not wiped prior to closing the door. In some cases, the door was not wiped at all.
7. Operators spray and rub their gloves with (b) (4) while holding (b) (4) wipes which are later used to wipe down the equipment and doors prior to leaving the Class 100 area. In some case the operator failed to sanitize gloves prior to entering the Class 100 area.
8. The stopper hopper is periodically jarred to dislodge stoppers. The stopper hopper is located above open vials.
9. Ineffective contact of the (b) (4) wipe during surface wiping of equipment prior to leaving the Class 100 area.
10. Excessive movement and talking in the Class 10,000 areas during filling operations. The stopper bag is kneaded and manipulated multiple times in the class 10,000 area located immediately adjacent to the class 100 area prior to addition. This could potentially lead to particulate contamination from the stoppers. Operators were also seen stretching in the Class 10,000 immediately adjacent to the aseptic filling area.

B. The interventions performed during media fills are not based on historical data from filling operations. Media fills are not reflective of routine operation.
   1. Inherent interventions are not tracked or trended in routine production. Only corrective and critical interventions are documented. Management admitted that they only perform the interventions required by the media fill. For example, they would only perform the addition of (b) (4) stopper bags in a media fill even though (b) (4) stopper bags might be added during routine production. Likewise, they would only perform fallen vial interventions in a media fill if a vial falls regardless of how many fallen vial interventions occur during routine production. They do not simulate any interventions.

      We compared the number of interventions performed during production by watching production videos of set-up and filling performed on the (b) (4) aseptic/(b) (4) sterilized line and noted the following discrepancies:

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Video watched	Type	Name	# Doc.	# Performed
Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858, dated 3/30/18	Inherent	Various	NA	Unknown
	Corrective	(b)(4) Spill cleanup / line sanitation	0	(b) (4)
	Corrective	(b)(4) Adjusting (b) (4)	0	
	Corrective	(b)(4) Adjust stopper (b) (4) (b)(4) times	2	
	Corrective	(b)(4) Removal of jammed stoppers post filling	0	
		(b) (4) Adjust Change Parts	0	
Diltiazem Hydrochloride Injection, 5 mg/mL, 10 mL vial, lot 041248, dated 4/6/18	Inherent	Various	NA	Unknown
Methadone HCl Injection USP 10mg/mL, 20cc vial, batch 041328 filled on 04/05/2018	Inherent	Various	NA	Unknown
	Corrective	(b)(4) Stopper (b) (4) Adjustments	0	(b) (4)
Midazolam Injection, USP, 5 mg/mL, 10 mL Fill / 10mL Vial lot no. 041228 which was filled on 4/5/18	Inherent	Various	NA	Unknown
	Corrective	(b)(4) Removal of jammed stoppers post filling	0	(b) (4)
	Corrective	(b)(4) Adjusted needle carriage	2	
	Corrective	(b) (4) (b) (4) adjustment	0	

2. Media fill time is calculated (b) (4) . (b) (4) (b) (4) AA204 Media Fill Process Simulation Program procedure states the filling operation must last a minimum of (b) (4) and will (b) (4) the maximum filling time. The fill line (b) (4) , and (b) (4) (b) (4) needs to be present. This does not reflect routine production. Media fill (b) (4) performed on 1/5/18 reports the fill time as (b) (4) and (b) (4) , however there was cycling times for (b) (4) and (b) (4)

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C. AA243 Aseptic Processing Qualification and Badge Control procedure states participation in the media fill is to be consistent with the nature of the duties of the person during routine production.

1. The procedure does not define what activities need to be performed by the employees to pass the media fill requirement. Management stated operators need to perform (b) (4) (b) (4) in a media fill to be qualified to work in the aseptic filling area. Although documented, the activities of the media fill participants are not tracked. During media fill (b) (4), dated 7/25/2017 for aseptic line (b) (4) QA personnel (b) (6) production operator (b) (6) and engineering technician (b) (6) did not perform any interventions but were still considered qualified. Production operators (b) (6) and (b) (6) performed (b) (4) and were present in the media fill for (b) (4) minutes respectively. All were considered qualified by this media fill.
2. Set-up and aseptic connections do not have to be performed by an operator in a media fill prior to being qualified to perform these activities in the aseptic filling area. The set-up and aseptic connection prior to the filling of Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858, performed on March 30, 2018, was performed by (b) (6) and (b) (6) Neither of these operators have performed this activity in a media fill.

D. Smoke studies are not representative of all activities:

1. The Airflow Visualization Study Report for the aseptic filling room (b) (4) and (b) (4) (b) (4) room (b) (4) smoke studies are deficient in that:
   - The (b) (4) set-up does not demonstrate unidirectional airflow when two doors are open. Two doors being open is not simulated in the smoke studies. Two open doors are needed during set-up of the (b) (4).
   - Not all interventions are simulated, i.e. adjusting (b) (4), removal of jammed stoppers post filling and shaking of the rubber stopper hopper.
   - The smoke study does not show unidirectional air pattern during the addition of stoppers as the hopper blocks all air flow from the filled vials located directly below. The Airflow Visualization Study Report Filling Room (b) (4) and (b) (4) (b) (4) Room (b) (4) dated 10/31/16, states "Air flow sweeps over technician in a downward direction and out toward the air return". The smoke study did not address

the open vials located directly below the hopper. Although not simulated during the smoke study, the filling line can be moving during stopper addition.

2. The smoke studies for line (b)(4) were deficient in that not all interventions were simulated including:
   - Intervention under the curtain with (b)(4) people
   - Full body intervention at the stopper bowl

   These interventions were seen during the video review of the filling of Fluorescein Injection, lot 031878, dated 3/26/18.

E. On 04/17/2018, during our initial evaluation of (b)(4) wipes from Lot# (b)(4), used in the Class 100 Filling Room (b)(4) we found holes in the outer packaging which were initially thought to be a sterility issue as only the outer package is sprayed with (b)(4) (b)(4) prior to entering the aseptic area. Preliminary results from the firm's investigation indicates that the supplier notified the firm that the outer barrier was never intended by the supplier to be a sterile barrier. The firm's current procedures do not account for this as the inner package has previously never been subjected to decontamination efforts prior to entering the cleanroom environment or upon opening in the aseptic area.

Repeat observations from 11/2004, 9/2006, 8/2007, 6/2009 & 2017

Observation 2

Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.

SOP EM127 Environmental Monitoring Program for Grand Avenue procedure specifies the specifications for environmental and personnel monitoring.

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A. The following discrepancies were noted during personnel monitoring:

1. Adequate scientific justification for holding the recovery rates for personnel working in the Class 100 area to Class 10,000 requirements was not provided. Per the SOP, the action level is set at 2 colony forming units (CFU) for the gloves and forearms in the Class 100 area where personnel perform critical interventions during filling, line set-up, and other aseptic activities.

2. No alert levels are listed for gloves, forearms or gowning. SOP EM127 requires the identification of CFUs over action or alert levels. This means the firm does not identify all CFUs obtained on operators working in the class 100 area. Adequate justification could not be provided for allowing 1 CFU on the operators who perform Class 100 interventions without any potential follow-up. These instances are not tracked or trended.
   - First quarter 2017: 611 positive samples were obtained on the gloves, forearms and gowning of operators working in the class 100 aseptic area. Of these, 103 were categorized as over action level. A total of 203 plates were identified resulting in a minimum of 408 positive samples not being identified or trended.
   - Second quarter 2017: 636 positive samples were obtained on the gloves, forearms and gowning of operators working in the class 100 aseptic area. Of these, 90 were categorized as over action level. A total of 148 plates were identified resulting in a minimum 488 positive samples not being identified or trended.
   - Third quarter 2017: 488 positive samples were obtained on the gloves, forearms and gowning of operators working in the class 100 aseptic area. Of these, 70 were categorized as over action level. A total of 125 plates were identified resulting in a minimum 363 positive samples not being identified or trended.
   - Fourth quarter 2017: 510 positive samples were obtained on the gloves, forearms and gowning of operators working in the class 100 aseptic area. Of these, 15 were categorized as over action level. A total of 76 plates were identified resulting in a minimum 434 positive samples not being identified or trended.

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3. PM monitoring takes place immediately following aseptic connections and setup per AA273 Room (b) (4) Interventions procedure, revision 4, dated 1/29/18 and AA143 Aseptic Technique procedure, revision 32, dated 4.9.18. During the review of the videos for the set-up, and aseptic filling of Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858 on March 30, 2018, Methadone HCl Injection USP 10mg/mL, 20cc vial, batch 041328 filled on 04/05/2018, and Midazolam Injection, USP, 5mg/mL, 10mL fill/10mL vial filled on 4/05/2018, the operators who performed the aseptic connection wiped their gloves with (b) (4) prior to being monitored.

   As a level of 1 CFU is acceptable for gloves and forearms during aseptic personnel qualification, 1 cfu obtained after aseptic connection would not be investigated. 1 cfu was obtained on the operator who performed the aseptic connection 7/28/17 for product code 629, Clindamycin Injection 600mg, lot 071097.

B. You do not perform environmental monitoring (EM) sampling in all appropriate locations. Specifically, in the Aseptic (b)(4) Fill Room, you perform surface sampling (b) (4) plates) in multiple areas; however, you do not perform surface sampling (b) (4) plates) on all significant objects which are touched and/or handled during filling operations. For example:
   - There are (b) (4) plastic containers which are used as reject bins for the rejected product. These bins are periodically picked up during processing operations and are not included in your EM program.
   - You have a stainless-steel stool which is used throughout manufacturing process operations and can be moved throughout the filling activities. This stool is not included in your EM program.
   - You have a stainless-steel frame which you attach plastic bags to which is used as your trash receptacle. You do not include this frame as a part of your EM program.
   - There is a hand held electrical device which is used during filling operations which is

attached to a plastic cord which is not included in your EM program. The hand held device is not monitored.

C. The firm has not established a sufficient understanding of the microbial flora existing in the aseptic core. The following discrepancies were noted during environmental monitoring:

1. Scientific justification could not be provided for the frequency of environmental monitoring:
   - Filling Support (Class 10,000 (ISO 7) Areas (this area includes the area immediately surrounding the Class 100 (ISO 5) aseptic filling) do not use settle plates during filling and instead perform (b) (4) monitoring. This monitoring can be performed at any time during production in the (b) (4) aseptic filling room. For example, Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858 was set-up from (b) (4) to (b) (4) and filled from (b) (4) to (b) (4) on March 30, 2018. (b) (4) monitoring plates were taken between (b) (4) to (b) (4)
     - (b) (4) (21%) took place prior to (b) (4) ((b) (4)).
     - (b) (4) (36%) took place prior to (b) (4) (b) (4)).
     - (b) (4) (71%) took place prior to (b) (4) ((b) (4) left to fill).
   - Formulation Areas (Class 10,000 (ISO 7) and 100,000 (ISO 8)) and other Class 100,000 (ISO 8) support areas -(b) (4) (dynamic) for (b) (4) and particulate (viable and non-viable air).
   - (b) (4) monitoring is performed (b) (4) for anaerobic organisms in the Class 100 area while filling is occurring. The (b) (4) monitored are (b) (4) (b) (4) by personnel and include (b) (4) that directly contact sterile parts.

2. Changing rooms are monitored (b) (4) times per (b) (4) per procedures and not during (b) (4) conditions. The (b) (4) data is used to justify the environment in the (b) (4) and (b) (4) changing rooms used during aseptic filling performed on the (b) (4) line. For example, monitoring of the (b) (4) and (b) (4) changing rooms was performed on 3/29/18 between (b) (4) to (b) (4) when (b) (4) was taking place, in support of the aseptic filling of Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858 on March 30, 2018.

Repeat observation from 11/2004

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Observation 3

An annual report did not include a full description of the manufacturing and control changes not requiring a supplemental application, listed by date in the order in which they were implemented.

A. The FDA was not notified that you ceased to test Acetylcysteine Injection 200mg/mL for L-Cystine and L-Cysteine impurities. This has been ongoing since 2016.

The 2016 Annual report lists the L-Cystine and L-Cysteine impurities as pending on the 6 months' stability reports for lots 051295LTT and 051315LTT. The stability tables were signed 5/13/16. The L-Cystine and L-Cysteine impurities were due for 6 months' stability analysis on 12/19/2015.

The 2017 Annual report had the L-Cystine and L-Cysteine impurities removed from the 18 months' stability study reports for lots 051115LTT, 051295LTT and 051315LTT although these impurities were still listed on the specification. The reports submitted to the FDA differs from the stability reports reviewed at the firm from this same time period for the same lots. These reports lists the L-Cystine and L-Cysteine impurities as (b) (4)

B. A critical processing equipment change was made which affected the following eight products manufactured at your facility when your processing operations were changed from the use of a (b) (4) to your (b) (4) for (b) (4) sterilization operations.

Product Name	Application No.	Date of Approval
Midazolam HCl Inj.	ANDA 75-494	6/30/00
Orphenadrine Citrate Inj.	ANDA 40-484	5/24/06
Adenosine Inj.	ANDA 78-076	10/31/08
Levofloxacin Inj.	ANDA 91-644	6/20/11
Ephedrine Sulfate Inj.	NDA 208-609	3/1/17

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Product Name	Application No.	Date of Approval
Fentanyl Inj.	NDA 16-619	2/19/68
(b) (4)	NDA(b) (4)	(b) (4)
Fluorescein Inj.	NDA 22-186	8/14/08

Your processing change began with Fentanyl Citrate Inj. lot no. 051087 in 7/2017. Your Annual Report for Fentanyl Citrate Injection, 50 mcg/ mL, 2 mL, 5 mL, 10 mL, and 20mL Ampules (NDA no. 016-19) dated April 11, 2018 does not include the change in(b) (4) sterilizing (b) (4) made from the(b) (4) to the (b) (4). You also did not include information regarding the equipment's processing capacities for each (b) (4) along with your qualification work performed to support the use of the(b) (4).

Observation 4

Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment used to produce aseptic conditions.

The inspection revealed numerous instances where your operators did not follow AA245 Cleaning & Sanitization of Manufacturing Areas, revision 40, designed to clean and disinfect the critical areas of the aseptic processing room. Specifically,

A. SOP AA245 specifies that machine sanitization in the class 100 area consists of (b) (4) cleanings, ancillary (common use) equipment consists of (b) (4) sanitizations and floor cleanings can vary from (b) (4) to (b) (4) cleaning. During a review of the following videos of cleaning, the following data integrity discrepancies were noted. These discrepancies were confirmed by the Production Manager:
   - Cleaning performed after the filling of Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858 on March 30, 2018: although documented as being performed, only (b) (4) of the (b) (4) cleanings were executed on the machine, none on the ancillary (common use) equipment and only (b) (4) of the (b) (4) cleanings was performed on the floor.

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- Cleaning performed on 4/10/18 after the filling of Hydralazine 2mL Vial, lot 041478: Although documented as being performed, common use equipment (b) (4) stand, garbage frame) was not cleaned, and only (b) (4) of the (b) (4) cleanings were performed on the floor.
- Cleaning performed after the filling of Methadone HCl Injection USP 10mg/mL, 20cc vial, batch 041328 filled on 04/05/2018: Although documented as being performed, only (b) (4) of the (b) (4) cleaning were executed on the machine.
- Cleaning performed after the filling of Midazolam Injection, USP, 5 mg/mL, 10 mL Fill / 10mL Vial lot no. 041228 filled on 4/5/18: Although documented as being performed, common use equipment (cart, (b) (4) stand, garbage frame) was not cleaned.

B. Floor and wall cleanings are not performed using the (b) (4) system (b) (4) (b) (4) , or using (b) (4) per procedure for all videos reviewed. Common use equipment is not moved to access the entire surface of the walls and floors during cleaning.

C. Cleaning is not performed from most critical area to least critical area, from top to bottom and from least dirty to most dirty per AA245.

D. Cleaning was documented as being performed in (b) (4) locations by the same Operator on April 7, 2018. The aseptic filling room is comprised of (b) (4) rooms (b) (4) During the review of the common use equipment used in (b) (4) , the operator documented cleaning the (b) (4) shelf, (b) (4) cart, (b) (4) stand, reject cart, (b) (4) cart, (b) (4) garbage, two step stools, and three (b) (4) stands with (b) (4) on (b) (4) followed by (b) (4) on (b) (4) in (b) (4) The same operator cleaned the (b) (4) shelf, (b) (4) stand, (b) (4) parts carts, (b) (4) carts, (b) (4) carts, the (b) (4) garbage frame, and (b) (4) stands with (b) (4) on (b) (4) and (b) (4) on (b) (4) in (b) (4)

E. An operator was observed stepping onto the (b) (4) Class 100 work area during tear down to remove the (b) (4) . Prior to stepping back out of the class 100 area, the operator scrapped off the bottom of their shoe.

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Observation 5

Failure to maintain complete data derived from all testing and to ensure compliance with established specifications and standards pertaining to data retention and management.

A. The qualification of the (b) (4) aseptic line could not be provided. 8-2-PQLFEM-06 Performance Qualification Lyophilization Facility Environmental Monitoring protocol dated 1/13/06 states "(b) (4) (b) (4) Only the (b) (4) interim report could be provided. During this time, 238 samples were inadvertently not taken. Deviation 6 was written on 7/31/06 regarding the (b) (4) and (b) (4) reports not being written. The deviation stated "(b) (4) (b) (4) There is no evidence that this was completed.

B. The video corresponding to Media, Vials (Area (b) (4) – Peristaltic Pump 10mL Vial batch record, lot (b) (4), dated 8/23/17 could not be located.

C. The video files (b) (4) through (b) (4) corresponding to Media, Vials (Area (b) (4) 2mL vial batch record, lot (b) (4), dated 1/5/18 could not be located.

D. Testing documents for the Atropine Sulfate API and (b) (4) used in Atropine Sulfate Ophthalmic Solution, USP lot 011037A. Atropine Sulfate API is tested (b) (4) and (b) (4) is (b) (4) Management could not find the electronic data from the testing of Atropine Sulfate API.

E. Integration of HPLC chromatograms is performed using (b) (4) and (b) (4) data system. This results in (b) (4) (b) (4). The

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(b) (4)
(b) (4)

Observation 6

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning bacteriological contamination and/or significant chemical, physical, or other change or deterioration in a distributed drug product. Specifically,

A. Testing of your Indocyanine Green (trade name IC Green) NDA no. 11-525, retain sample lot numbers 021656, 31206, 041136, 051216 and 061486 identified a downward trend for the pH results for these lots of product. You failed to submit a Field Alert Report regarding this trend along with initiate an investigation and/or initiate corrective and preventive actions regarding this incident.

B. On 3/22/18, your Customer Complaint Investigation PR # 78593 documented your findings of "some dark spots/mold on the (b) (4) in two lots of (b) (4) (b) (4) (ANDA (b) (4)) batches (b) (4) (b) (4) batch (b) (4)) and (b) (4) (b) (4) batch (b) (4) . You failed to notify your customer for this product in a timely manner which would allow them to submit an NDA Field Alert within the required timeframe, as this notification was not done until 4/17/18 which was a result of this establishment inspection.

C. The FDA was not notified when the (b) (4) months stability testing for Acetylcysteine Injection 200mg/mL was not executed for (b) (4) Assay due to method issues.

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

Observation 7

Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed. The investigations do not always include conclusions and follow-up.

A. Inadequate investigations were noted during the review of OOS/OOTs obtained during personnel monitoring. The firm uses (b) (4) to address OOT or action levels obtained during personnel monitoring. What is reviewed during a (b) (4) is not governed by a procedure. Management explained the operator gowns (b) (4) (b) (4) . No monitoring is performed. The date of the (b) (4) is documented but not (b) (4) or (b) (4)

Investigation 71675, dated 10/25/17, identified an over action result obtained during personnel monitoring of production operator (b) (6) exiting the aseptic filling room (b) (4) at (b) (4) , with 10 cfu on his chest (action level (b) (4) during the filling of (b) (4) Eptifibatide, lot 101107 on 10/16/17. (b) (6) performs interventions in the Class 100 area. The investigation determined (b) (6) had an action level recovery rate of (b) (4) %. Due to the high recover rate, CAPA 72529 was initiated to track (b) (6) 's retraining on aseptic procedures and (b) (4) . The results of the (b) (4) (b) (4) is not documented. Training was completed on 11/21/17 and QA approved on 11/27/17. During the execution of CAPA 72529, (b) (6) continued to work in the filling room on 10/30/17, 10/31/17, 11/03/17, 11/6/17, 11/7/17, 11/8/17, 11/9/17, and 11/15/17.

During this time (11/8/17), investigation 72771 was initiated regarding an over action result obtained during the PM monitoring of (b) (6) exiting the filling room (b) (4) at (b) (4) , 4 CFUs on his chest (action level (b) (4)) during the filling of (b) (4) Cyclopentolate, lot 101347 on 10/31/17. His 'action level' recovery rate was determined to be (b) (4) % and his 'total personnel bioburden recoveries greater than (b) (4) ' was (b) (4) %. This exceeded the recovery rate specifications set by the firm. CAPA 74623 was triggered stated (b) (6) will be monitored and (b) (4) by a production

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(b) (4) . CAPA 74623 was completed on 1/26/18 and QA approved on 2/6/18. During the investigation, (b) (8) continued to work in the aseptic core.

While these investigations were still ongoing, investigation 73441 was initiated on 11/16/17 for (b) (4) due to the fact (b) (4) monitoring occasions showed colony forming units below action level at the same site number. Due to the ongoing investigations mentioned above, this investigation just references CAPA 74623.

Effectiveness checks are not performed on CAPAs related to personnel monitoring.

B. Investigation 66336, dated 8/21/17, regarded the failure to complete replicated interventions listed in the media fill simulations for:
   - Media fill (b) (4) dated 7/25/17, Line (b) (4)
   - Media fil (b) (4) dated 7/2/17. Line (b) (4)
   - Media fil (b) (4) , dated 7/27/17, Line (b) (4)
   - Media fill (b) (4) dated 7/28/17, Line (b) (4)

The impact was categorized as *"There is no product impact. All, currently supported, interventions listed in the Media fill records were still performed a number of times that, when normalized, is representative of an aseptic fill process. On all Media fills, more interventions are performed in a shorter period of time, than the worst case scenario of a commercial run."* No data could be provided to support this statement. Batch records were not reviewed to determine the number of critical and corrective action interventions during routine production. Inherent interventions are not tracked during routine production. Management stated this statement was based on review of a risk assessment for filling line interventions performed on 6/30/2016.

This risk assessment for filling line interventions, dated 6/30/16 was not supported by data. Management stated batch records were not reviewed for this assessment. Management stated the

risk assessment was based on conversations with SMEs. Who was interviewed was not documented.

C. Laboratory events and void analytical errors are not tracked or trended. This has resulted in problems with test methods/equipment/analysts not be investigated. For example, an investigation was not initiated into the evaluation of (b) (4) (b) (4) in Pilocarpine Hydrochloride Ophthalmic Solutions method. Suitability could not be obtained during the running of this method and numerous (b) (4) were executed over a short period due to being unable to obtain adequate chromatography to start suitability. (b) (4) were confirmed as being (b) (4). Lab events were triggered for these runs, but these events were not tracked or trended.

Date	Sequence	# of injections	Lab Event
8/9/17	(b) (4)	(b) (4)	65299
8/9/17			
8/10/17			69147
8/16/17			
8/23/17			
8/28/17			
8/31/17			
9/7/17			68228
9/8/17			
9/15/17			68864
9/18/17			
9/18/17			
9/20/17			69147
9/21/17			
9/21/17			

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At this time, an informal investigation (outside of (b) (4)) was initiated in QC with sequences being run on 10/2/17, 10/3/17, 10/6/17, 10/11/17, 10/16/17, 11/14/17, 11/16/17, 11/17/17. The informal investigation currently ongoing.

D. During review of the Investigation PR65403 opened 8/10/2017 due to an (b) (4) (b) (4) (b) (4) Alarm and later an (b) (4) Alarm for Non-Viable Particles during filling operations, I observed in the investigation report that the firm did not further address the unknown cause of the (b) (4) alarm reported. The (b) (4) Alarm occurred 08/09/2017 (b) (4) – Trays (b) (4) were segregated/rejected. The (b) (4) occurred at (b) (4) Trays (b) (4) were segregated. These were later released from hold. The root cause for the (b) (4) was found to be due to personnel in the area when the fill line had stopped. However, the root cause of the (b) (4) alarm remains unknown and was not further investigated or addressed in CAPAs.

E. During review of complaint investigation PR67417 for Brimonidine Ophthalmic Solution –the firm did not conduct retain sample review adequately to mimic the conditions reported in the complaint. The complaint reported that after the customer placed the dose in his eyes and set the bottle down on the table the drug product was observed to be coming out of the tip. However, during the course of the investigation at Wykles, (b) (4) retain samples were inspected for leaks. When I interviewed the Quality Manager at Wykles, he stated that the retain sample review conducted for this investigation as well as others consisted of checking for leaks by inspecting the outer bottle for damage. This type of perfunctory examination of the outer container is not consistent with the type of issue reported in the complaint.

F. Brimonidine complaints such as PR77856 for "difficult to deliver drug product" are not completely investigated. The firm is using only a reference to their Global Investigation 2014-06 to address these complaint issues. Global investigation 2014-06 references a peer review study suggesting that wetted tips (more frequent/daily use) delivered product more efficiently than periodic use. This indicates that the plastic remains malleable and assists in the correct delivery of drug product. However, the firm is not confirming that these situations reported in the peer

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review are applicable to the complaint issue. The firm uses the peer review to justify why no CAPAs for these types of complaints are being initiated.

G. During review of the CAPA 69622 which was initiated in response to Investigation #PR66072 – Personnel Bioburden from a fill room Tech recovery on forearm resulting in a "(b) (4) " of 2 cfus during exit monitoring after filling operations commenced, the CAPA addressed (b) (4) of the employee. However, no effectiveness check was put in place to test the effectiveness of the corrective action.

H. Complaint no. 78593 was opened 1/23/18 after receiving a complaint for (b) (4) (b) (4) lots of product which were observed to have moldy packaging. As a part of your investigation for this complaint you failed to do the following:
- Speciate the mold found on the secondary packaging materials (b) (4) which you found during your review of retain samples maintained at your facility.
- Document in your investigation how many units were found to have mold on them for the different reserve lots (b) (4)) of (b) (4) where the mold was found.
- Contact your customer to notify them of the mold you identified in your reserve samples so that they could complete their regulatory obligations in a timely manner.
- Expand your investigation to evaluate other products which used the same lots of packaging material as the (b) (4) product to determine if other products were affected.
- Include in your investigation for this "moldy event" the evaluation of the packaging material the mold was identified on.

I. Nonconformance Report no. 61664 was opened on 6/23/17 when your Quality Assurance Unit was not notified when Fentanyl (b) (4) lot 051087 skid no (b) (4) was brought to the inspection area

for verification of incoming product identity and batch number. CAPA 63662 was opened on 7/20/17 to evaluate the in-coming product check process for procedural enhancement with assistance from the Quality Assurance to ensure checks are appropriately completed and implement procedural enhancement to SOP W1101 "Inspection Area Set-Up, (b) (4) (b) (4) Verification, Operation and Clearance" and SOP WP157 "Packaging Line Preparation and Completion". You have not completed a timely Effectiveness Check reported in document no. 75064 to verify the effectiveness of your changes.

J. Nonconformance no. 53767 was opened 3/27/2017 after Indocyanine Green (trade name IC Green) NDA no. 11-525, lot number 021516 stability sample failed stability for pH at 12 months. The out of specification result (OOS) was 5.3 with your specifications being (b) (4) to (b) (4) As a part of your investigation you tested retain samples within expiry at the time of the OOS results for lot 021516. After this evaluation, you initiated CAPA no. 58383 opened 5/16/17 where you identified five (5) retain lots which you continued to evaluate for lots 021656, 31206, 041136, 051216 and 061486. On 8/ 10/17 you closed your CAPA No. 58383 stating "there is no downward trend in any of the batches". You continued to test these 5 lots of product for an additional (b) (4) to (b) (4) timepoints and a downward trend is present for each of these lots of product. You failed, however, to initiate an investigation regarding this trend and initiate corrective and preventive actions associated with this trend.

Repeat observation from 11/2004, 9/2006, 8/2007, 6/2009, 5/2013. 6/2016

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Observation 8

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.

A. The HEPA filters used in the class 100 area are not periodically monitored for uniformity of velocity across the filter relative to adjacent filters. Velocities of these filters are not correlated to the velocity range established at the time of in situ air pattern analysis studies.

B. The stopper hopper is located on the far side of the filling area. To reach the hopper during the addition of stoppers, (b) (4) (b) (4) which can be accessed by operators. Exposed vials are not removed and the line can be moving during the addition of stoppers. Management confirmed the design of the line was not ideal.

C. The filling lines are not designed for ease of cleaning. The filling lines are set several inches off the floor making it difficult to clean underneath:
   - (b) (4) line (aseptic filling) is located (b) (4) off the floor
   - (b) (4) ine (ophthalmic filling) is located (b) (4) off the floor
   - (b) (4) line (b) (4) sterilized) filler is located (b) (4) off the floor
   - Line (b) (4) filler (ampule) is located (b) (4) off the floor

Repeat observation from 9/2006, 8/2007, 4/2017

Observation 9

Each container or grouping of containers of components is not examined visually upon receipt and before acceptance for container damage, broken seals, or contamination. Specifically,

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A. Evaluation of Sterile Gloves: On 04/17/2018 during inspection of the sterile gloves the firm uses in the Class 100 Filling Room (b) (4) I observed several instances of packaging integrity issues and the presence of foreign matter within the package cavity. These gloves are sold in cases and in each case there are (b) (4) separate packs, each containing (b) (4) pairs of gloves. We inspected only one (1) package ((b) (4) pairs). The results of the visual inspection are as follows.

- 78% of the pairs had concerning issues. ((b) (4) of (b) (4) pairs).
- 34% of the pairs had potential bottom seal integrity issues (b) (4) of (b) (4) pairs).
- 70% of the pairs contained foreign matter such as plastic fragments, black, blue or red fibers, black or blonde hair (b) (4) of (b) (4) pairs).
- (b) (4) had more than 1 fiber observed (b) (4) had more than 3 fibers observed; (b) (4) had 6 fibers and a gap in the bottom seal.

B. Failure to inspect personnel and surface monitoring contact plates prior to use: During the tour on 4/10/2018, we observed that the (b) (4) contact plates the firm uses for environmental monitoring had defective (b) (4) fills. The (b) (4) did not appear to be (b) (4) and was unevenly distributed throughout the plate. The fill was uneven leaving the level of (b) (4) at or below the rim level of the plates for at least (b) (4) of the contact surface area. We visually inspected (b) (4) plates which had been used and found that 98% ((b) (4) of (b) (4) plates) of the plates had (b) (4) which was unevenly distributed in the plate where (b) (4) of the (b) (4) surface area was below the rim of the plate.

We reviewed (b) (4) plates which had not been opened from lot number (b) (4). This unopened package contained (b) (4) plates. I found that (b) (4) out of the (b) (4) plates had defects which included which includes being uneven (b) (4) and not domed (b) (4).

Observation 10

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

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A. Acetylcysteine Injection 200mg/mL requires the testing of (b) (4) and (b) (4) impurities during stability testing using (b) (4) (b) (4) in Acetylcysteine Injection 200mg/ml and Acetylcysteine solution by (b) (4) These tests have not been performed during stability testing since 2016. There is no assurance that the product remains in specification for the life of the product (2 years). This affected the (b) (4) commercial (validation) lots, plus the 2016 and 2017 annual stability testing. The firm has distributed (b) (4) lots of Acetylcysteine Injection. (b) (4) of these lots are still within expiry.

B. Management confirmed that the compendial methods used during the stability testing of finished drug product have not been proven to be stability indicating. The following methods have not been evaluated for peak purity and/or the methods ability to detect all unknown impurities:

Product	Method	Discrepancies
(b) (4)	(b) (4)	Not evaluated for peak purity Not evaluated for mass balance Not evaluated for peak purity
Lorazepam Injection,2mg/ml – vial 2 mg/mL – 1 ml fill		Not evaluated for peak purity
Lorazepam Injection,2mg/ml – vial 2 mg/mL – 1 ml fill		Not evaluated for mass balance Not evaluated for peak purity
Mycophenolate Mofetil for Injection USP, 500 mg/vial		Not evaluated for peak purity
Mycophenolate Mofetil for Injection USP, 500 mg/vial		Not evaluated for mass balance Not evaluated for peak purity
(b) (4)		Not evaluated for mass balance
Capastat Sulfate (capreomycin for Injection), 1g per vial, 10 ml vials		Not evaluated for mass balance Not evaluated for peak purity

Repeat observation from 8/2007

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Observation 11

Control procedures are not established which monitor the output of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically,

A. During the visual inspection process of your finished sterile injectable drug products the established descriptions for packaging defects includes Foreign Matter. You have not established a baseline for what the foreign matter in your products are along with identifying in your processing records the different kinds of foreign matter found during your visual inspection operations (i.e. white particulates, black particulates, red/brown particulates, glass particulates, metallic particulate, etc.). You also do not maintain documentation for the containers reviewed by your technicians during their review of your product for rejects.

B. You have also identified High/Low Fill Weights as one of the defects being evaluated during your visual inspection process. You have not, however, established alert and/or action limits for this defect. This is significant as potential discrepancies in fill weight will not be investigated. For example, during the visual inspection of Ketamine HCl Injection, USP, 100 mg/mL (Base), 10mL vial, lot 031858, 878 vials were rejected for low fill weights although all fill weights passed inspection during filling.

Repeat observation from 11/2004, 9/2006 & 6/2016

Observation 12

Employees engaged in the manufacture, processing, packing, and holding of a drug product lack the training required to perform their assigned functions.

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A. Set-up and the aseptic connection for aseptically filled Ketamine HCl Injection, USP, 100mg/mL (Base), 10mL vial, lot 031858 from March 30, 2018, was performed by (b) (6) and (b) (6) Neither of these operators have been certified to perform this activity.

B. The following employees have performed set-up/aseptic connection in a media fill prior to completing their job certification on AA234 Safety, Set-up and Operation of the (b) (4) Filler: (b) (6)

Repeat observation from 8/2007

Observation 13

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration. Specifically,

During your annual review of reserve samples maintained at your facility your documentation for this review does not include the name of the employee who performs the review of the specific reserve samples. Your reserve sample review documentation lists all employees who were involved in the review of that product at the bottom of the page and does not include the date the reserve lot was reviewed along with the name of the person performing the review for the individual lots reviewed. In addition, the documentation does not include the types of defects the reserve samples are being evaluated for along with information on how many defects are identified during this review.

x Michele Perry Williams x Sandra A Hughes x Michele L Glendenning

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