

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

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 7/23/2018-8/30/2018*
	FEI NUMBER 2246848

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael P Stehn, Vice President and General Manager

FIRM NAME Akorn Inc.	STREET ADDRESS 72 Veronica Ave
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-3426	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:
QUALITY SYSTEM**

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,

- A) Azelastine Hydrochloride Ophthalmic Solution, 0.05% (Sterile) batches 6K89A, 6K90A, 6K92A failed CRT stability testing for multiple time points (6M, 9M, 12M, 18M); these batches remained in the market until they were recalled during the current inspection. Investigation PR# 58999 into the failure of batch 6K89A was initiated on 05/23/2017 after the 6M stability time point failed for the impurity (b) (4) with a result of 0.6% (Specification Limit: (b) (4)). The stability data for these time points was not readily available for review during the beginning of the inspection. We observed that the employees started filling the notebook pages and certificate of analysis during our inspection. The QC Manager stated that the delay was due to the observance of failing stability results and the need to complete investigations and perform recalculations.

For example, original stability results obtained for Azelastine Hydrochloride Ophthalmic Solution, 0.05% (Sterile) batch 6K89A, (b) (4) Impurity were modified or recalculated later and new entries were made into laboratory notebooks during the current inspection as shown in the table below:

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Azelastine HCl OS, Stability Test (Lot#6K89A)	Original Result & Date	Original Notebook #	Modified Result & Date	Modified Notebook #
3M CRT, Impurity: (b) (4)	0.4% (04/11/2017)	17-001 (p.188)	0.2% (07/30/2018)	18-006 (p.4)
6M CRT, Impurity: (b) (4)	0.6% (05/22/2017)	17-026 (p.100)	0.4% (07/30/2018)	18-006 (p.129)
9M CRT, Impurity: (b) (4)	0.6% (12/29/2017)	17-091 (p.29)	0.7% (07/31/2018)	18-006 (p.131)
12M CRT, Impurity: (b) (4)	0.7% (02/20/2018)	17-091 (p.102)	0.5% (07/31/2018)	18-049 (p.4)
18M CRT, Impurity: (b) (4)	0.7% (07/11/2018)	18-006 (p.90)	0.9% (07/31/2018)	18-006 (p.121)

Similarly, OOS results were also obtained for Lot# 6K90A, 6K92A and the same practice of modifying the results and notebooks during the current inspection was observed.

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B) Investigation PR# 74716 was issued because Ciprofloxacin OS USP, 0.3% Lot# 6D68A failed stability testing at the 18M expiry time point on 11/30/2017 for the Impurity (b) (4) (Specification Limit: (b) (4) %, Result: 0.3%). The investigation confirmed the OOS result, however, testing at earlier stability time points such as 9M and 12M demonstrated the presence of Impurity (b) (4) and were rounded down (as per procedure 30-008 Version 8: Good Documentation Practices, section 7.15) to meet the specification limit. Another Ciprofloxacin OS USP, 0.3% batch, 6M66A held as a retention sample was tested on 05-30-2018 (approximately 17 months after production) as part of this investigation and failed for the largest known impurity with a result of 0.3 % (Specification Limit: (b) (4) %). The investigation failed to review and consider additional stability tests for other Ciprofloxacin OS USP, 0.3% lots on the market to assure the stability of the product beyond the 12M time. Ciprofloxacin OS USP, 0.3% Lot# 6D68A was the only lot placed on stability for calendar year 2016 and thus represented approximately (b) (4) released lots on the market that year.

C) Investigation with PR # 84110, which was conducted for the assessment of trial injections that were found to have been a common practice in the Quality Control and R&D laboratories up through May 2018, is inadequate. Deficiencies we found in this investigation include, but were not limited to, the following:

- The investigation included a review of injections with the word "trial." Our limited review of the injections from your (b) (4) chromatography systems found numerous additional injections with anomalous names that have not been reviewed, such as: "Trail", "sample," "No injection," "test," "S2," "S1," "Imp," "DP," "Sample-1," "Sample-2," "Sample-3," "Trai Deg," "Sample-Assay-1," "Sample-Assay-2," "Sample-Assay-3," "Sample-Assay-4," "Sample-Assay-5," and "Sample-Assay-6." Based on the additional injections with anomalous names that were found to not have been reviewed and the widespread practice of performing trial injections in the QC and R&D laboratories, there is limited assurance in the reliability of data submitted to the Agency and generated for commercial batches.

Note: The practice of performing trial injections prior to the official analyses was

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discussed during the 2015 inspection. No corrective measures to prevent this practice were implemented until 05/2018. Furthermore SOP 73-034 LC Data (Version 4) allows samples to be used as trial injections as per section 5.3.3.

- In our review of Event # 18 of the investigation, in which a trial injection of an API sample (named as "Trial Sample") of Hydroxyamphetamine Hydrobromide was reviewed by the employees in the QC laboratory, we found that the result for this was OOS for Total Impurities (Specification Limit: (b) (4) %, Result: 1.0%). Additionally, we observed that the results for the official samples that were analyzed for Lots (b) (4), (b) (4) following the trial sample injection were also OOS (results of 1.6%, 1.9%, and 1.4%, respectively). The OOS results for both the trial and official injections were invalidated during the investigation based on a single passing retest result for each lot, without further follow up. Lots (b) (4) were used in the manufacture of finished product lots of Paremyd Ophthalmic Solution of which the following are still within expiry:

API Lot Number	Finished Product Lot Number	Finished Product Lot Expiration Date
(b) (4)	5L83A	October 2018
	5L83A	October 2018
	5M89A	November 2018
	6B60A	January 2019
	6B60A	January 2019
	7B54A	January 2020

D) Among the closed non-conformance investigations between 01/01/2017 and 07/24/2018,

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approximately 56 of the total (b) (4) Out-of-Specification (OOS) results ((b) (4)) were invalidated by assigning 'personnel error', 'instrument error', 'procedure', or 'other' as the root cause without adequately supporting with scientific evidence. The retested passing results were reported; however, the investigations were not extended to determine why the errors kept on reoccurring nor were effective CAPAs implemented to minimize these incidents going forward.

The following examples include, but are not limited to, OOS results that were invalidated by the Quality Unit without scientific rationale and supporting documentation:

1. Non-Conformance investigation, PR# 82845 was initiated on 3/13/2018 for OOS results for assay for Olopatadine HCl Ophthalmic Solution, 3M stability lots 7J13A (74.7%) and 7J15A (78.5%) (Specification: (b) (4) % and (b) (4) %). The investigation concluded that the root cause for the OOS was analyst error based on retested results. No supporting documentation was provided for the indicated root cause. For the twelve months prior to investigation PR# 82845, this same analyst was associated with an additional 14 OOS results that were all invalidated due to analyst error.
2. Non-Conformance investigation, PR# 85037 was initiated on 4/4/2018 for an OOS result of 0.3% (Specification: (b) (4) %) for the unspecified impurity for the finished product Olopatadine HCl Ophthalmic Solution, 0.1%, lot 8C90. The OOS result was invalidated through retesting and attributing the failure to human error (sample preparation error) and the batch was released on 04/17/2018. Although a similar OOS result was obtained for a previous batch produced in 07/2017 (7G41), Investigation PR# 64150 initiated on 7/26/2017 concluded human error as the root cause. No corrective actions were initiated after this repeated incident.
3. Non-Conformance investigation, PR# 86662 was initiated on 04/23/2018 for an OOS result of 330 mOsm/kg H₂O (Specification: (b) (4) mOsm/kg H₂O) for Osmolality for the Ketotifen Fumarate Ophthalmic Solution, 0.025%, stability lot 7C91A, 12M CRT. The OOS result was attributed to analyst error (procedure not followed) without any

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supporting documents and no corrective actions were initiated based on the investigation.

OBSERVATION 2

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

- A) On 05/04/2018, Investigation PR# 87904 was initiated for Lidocaine Jelly 5 mL aluminum tube, Lot (b) (4) (packaging container) due to observed metal shavings on 05/03/2018 and 05/04/2018 during filling line (b) (4) operations for Lidocaine Hydrochloride Jelly USP, 2% (Sterile) Batch 8E47B and Batch 8E47C. The aluminum tube supplier's investigation completed on 06/28/2018 disclosed that the shavings were minute and possibly missed by the end of line inspection personnel. According to PR# 87904, batches 8E47B and 8E47C are impacted and recommended for rejection. However, Batch 8E47A (05/02/2018) and Batch 8E47D (05/05/2018) that were manufactured during the same campaign were deemed to not be impacted due to no metal shavings being visually observed during the fill process. There is no specific procedure or instruction within the batch record for a visual check of metal shavings during the fill process. Investigation PR# 87904 initiated on 05/04/2018 and reviewed on 07/26/2018 during the current inspection did not extend to all serializations of the same parent tube lot ((b) (4) (b) (4)) used to manufacture released drug product batches. This includes the lack of thorough evaluation and filling line inspection for metal shavings for the following released drug product batches that used the same parent tube lot:

Product	Batch #	Aluminum tube lot #	Site Distribution Date	1 st Customer Delivery

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				Date
Lidocaine HCL 2% Jelly	8D12C	Lot (b) (4) and (b) (4)	04/18/2018	(b) (4)
Lidocaine HCL 2% Jelly	8D12B	Lot (b) (4)	04/18/2018	(b) (4)
Lidocaine HCL 2% Jelly	8B68C	Lot (b) (4)	04/04/2018	(b) (4)

Furthermore, Investigation PR# 87904 states that the metal shavings event is not similar to any other previous events. However, the investigation did not extend to other previous drug product filling incidents and potential root causes, such as filling line# (b) (4) where metal shavings and fine particles were observed for drug products filled dating back to 01/2017. For example:

1. Erythromycin Ophthalmic Ointment USP, 0.5%, Batch #8E65A, Exp.: 04/20, investigation initiated on: 05/15/2018 due to metal shavings found on the (b) (4) during filling line # (b) (4) operations causing OOS yields. The investigation noted that the root cause was not confirmed, but likely due to (b) (4) tubes used during filling operations. (b) (4) units that were observed to have shavings were rejected of the batch partially released on 06/26/18.
2. Erythromycin Ophthalmic Ointment USP, 0.5%, Batch #8D20A, Exp.: 03/20, investigation initiated on: 04/12/2018 due to shavings (fine particles) and low filling weight being observed during filling line # (b) (4) operations. The mechanic identified the metal shavings from the (b) (4), which (b) (4) (b) (4) units were determined to be impacted and rejected of the batch partially released on 05/25/2018.

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3. Sodium Chloride Ophthalmic Ointment 3.5g, Batch #7B74, Exp.: 01/20 investigation initiated on: 04/02/2017, due to metal shavings being found on the filling machine line table. The investigation attributed the possible root cause due to adjustments of (b) (4) to even the fold during filling operations. (b) (4) units were segregated and rejected of the batch partially released on 04/06/2017.
4. Logged incident, Dated: 01/08/2017: Erythromycin Ophthalmic Ointment 1g, Batch #7A23A, Exp.:12/18 due to possibility of particle (shavings) on top of (b) (4). No written investigation was performed as per to SOP 70-037-01 Investigations, Effective Date: 05/27/16 requirement.

At the time of review of the aforementioned investigations during the current inspection, there has been no metal identification test performed for instances of observed metal shavings and fine particles.

B) On 10/31/2017, a confirmed OOS osmolality result of 537 (specification: (b) (4) mOsm/kg H₂O) was obtained for Ketorolac Tromethamine 0.5% Ophthalmic Solution Sterile, 18 months CRT, Stability Batch #6C95A, Exp. Date: 02/2018. Investigation PR# 72072 was closed on 03/05/2018 and concluded that the damaged threads on the neck of the stability sample container (bottle# (b) (4)) led to evaporation of the aqueous portion of the subject drug product thereby artificially elevating the level of undissolved particles. A second investigation (PR# 72136) for this product was opened on 11/01/2017 due to observed volume of the final container (bottle# (b) (4)) for Batch 6C95A, 18 Months CRT being 50% lower than expected. A third investigation (PR# 82868) was also opened on 03/13/2018 due to stability samples for Batch 6C95A, 24 Months CRT having residue under the neckband. However, thorough evaluation of the filling line and tip insertion process was not conducted and documented as part of the three

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written investigations reviewed during the inspection. Instead the supply of the packaging containers (bottles) was assumed to be the probable root cause.

Based on the supplier's investigation, dated 8/2/2018, the firm plans to expand the investigation to evaluate additional batches manufactured using the filling line and tip insertion process.

Since November 2017, approximately (b) (4) batches of Ketorolac Tromethamine 0.5% Ophthalmic Solution Sterile, 0.5% have been manufactured and released to the market in addition to other ophthalmic drug product batches using this same equipment and tip insertion process.

Additionally, PR# 72136 opened on 11/01/2017 noted damaged bottle lot (b) (4) (packaging container) as the potential root cause for the 50% reduction in product volume, however, the investigation reviewed during the inspection did not extend to other released batches using the same parent bottle lot (b) (4). This includes approximately (b) (4) other lots of finished product such as Timolol Maleate 0.5% Ophthalmic Solution batch# 6B55A (expires 01/2019) and batch# 6C25A (expires 02/2019). Furthermore, the written investigation states that batches using bottle lot (b) (4) did not result in any complaints. However, the following complaints were queried during the current inspection and determined to be associated with drug products using bottle lot (b) (4)

1. Ketorolac Solution 5ML; 0.5%, Batch 6C95A, Complaint Received On: 05/26/2016 for empty sealed bottle.
2. Ketorolac Solution 5ML; 0.5%, Batch 6C95A, Complaint Received On: 09/21/2016 for empty bottle that was completely sealed.
3. Ofloxacin Ophthalmic Solution, Batch# 6C17A, Complaint Received On: 08/31/2016 for leaking.
4. Diclofenac Ophthalmic Solution, Batch 6C29A, Complaint Received On: 06/01/2016 for bottle not filled to capacity.

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OBSERVATION 3

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

Specifically,

Quality related activities and commitments are not completed within established timeframes, in part due to a lack of qualified personnel to complete the work. For example,

A) OOS Investigations, 52031, 53994, 57966 and 62320 were not closed after one year of opening the investigations. The Senior Manager Quality Systems stated that due to competing priorities they could not close these investigations in a timely manner.

1. PR#52031: Investigation was initiated on 03/07/2017 for OOS on Particle Size test for Erythromycin (Sterile), USP, batch# (b) (4). Investigation extension requests were made 9 times and approved without adequate justification.
2. PR#53994: Investigation was initiated on 03/29/2017 for OOS on Particle Size test for Polymyxin B-Sulfate raw material, batch# (b) (4). Investigation extension requests were made 6 times and approved without adequate justification.
3. PR#57966: Investigation was initiated on 05/10/2017 for OOS on Particle Size test for Neomycin Sulfate raw material, batch# (b) (4). Investigation extension requests were made 6 times and approved without adequate justification.

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4. PR#62320: Investigation was initiated on 06/30/2017 for OOS on Loss on Drying for Timolol Maleate USP raw material, batch# (b) (4). Investigation extension requests were made 6 times and approved without adequate justification.

B) HPLC data relating to an Azelastine impurity test, entered in Notebook NB-CH-17-91, pages 33-44 on 1/3/2018 was not reviewed for approximately 4 months. Also, HPLC stability data relating to Lubricant Eye Drops, entered in Notebook NB-CH-17-84, pages 99-100 on 12-18-2017 was not reviewed until 07-24-2018 (7-months delay). Furthermore, entries made in pages 87, 88 and 101 in December 2017 relating to Lubricant Eye Drops have not been reviewed until the current inspection. The QC reviewer (b) (6) stated that due to personnel resources issue, they could not review the notebooks in a timely manner.

C) Completed Laboratory notebooks and logbooks were not returned to QA documentation as required by written procedures, SOP#30-012, "Control of Forms, Logbooks and Notebooks" and SOP#73-033, "Use, Maintenance, and Auditing of Quality Control Chemistry Laboratory Notebooks" even after they met the (b) (4) active period. For example, Notebook NB-CH-17-01, issued to Chemist (b) (6) on 01-03-2017 has not been returned to QA Documentation even after last test was reviewed on 04/27/2017. More than 15 notebooks remain in similar status and have not been returned to QA documentation.

LABORATORY CONTROL SYSTEM

OBSERVATION 4

The written stability testing program is not followed.

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Michael P Stehn, Vice President and General Manager

FIRM NAME Akorn Inc.	STREET ADDRESS 72 Veronica Ave
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-3426	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

Specifically,

Stability studies are not completed in (b) (4) as stated in SOP 73-043 Version 15: Testing and Expiration Dating. Out of (b) (4) stability samples submitted to the lab from 01/2017 to 06/2018, at least 28% (b) (4) samples were completed after the (b) (4) timeframe. Furthermore, of the (b) (4) samples submitted, approximately 222 have an unknown status. For example, Lubricant Eye Drops batch 7A34A, the 9-month stability study sample was pulled on 11/02/17, last test start date 03/08/2018 and the C of A was closed on 07/31/18 (over 8 months later). The 12-month stability study sample for the same batch was pulled on 02/02/18, last test start date 04/04/2018 and the C of A was closed on 06/29/18 (over 4 months later). In addition, the Benzalkonium Chloride assay by HPLC for both the 9 month and the 12-month time points were conducted on the same day (03/08/2018; approximately three months late for the 9-month sample) in the same sequence.

OBSERVATION 5

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

- A) User roles assigned to laboratory personnel who use the HPLC and GC systems ((b) (4) software) in the Quality Control (QC) Chemistry Laboratory to test in-process, final release samples, and stability samples do not ensure appropriate controls over the software in that:
 - 1. The QC Supervisors and Reviewers are also assigned an Analyst role that enables them to edit sequences, manually process data, and edit (b) (4) report templates, which are used for system suitability and results.

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

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 7/23/2018-8/30/2018*
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2. Various (b) (4) Chromatography Data System report templates are used to calculate and present analytical results. However, no attempt has been made to validate any of these reports. In addition, there are no established procedures on creating (b) (4) reports and report validation.

B) Computerized systems in the QC laboratory do not have sufficient controls to prevent unauthorized access to, changes to, or omission of data files and folders. This includes the Fourier Transform Infrared Spectrophotometer (FTIR), Total Organic Carbon (TOC) and (b) (4) workstations. Electronic raw data files can be deleted from the computerized systems connected to these instruments, as demonstrated during the inspection. These systems are used to test in-process, final release and stability samples.

C) The data for analyses performed on the standalone laboratory instruments are not backed up. Your written procedure, 73-035 Version 00: Access to Configuration Software/Automated Process control Systems section 5.6.3.2 states "(b) (4) [redacted]". This includes the FTIR, UV-Vis spectrophotometer, TOC, (b) (4) Particle Counter and (b) (4) instruments.

OBSERVATION 6

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are not written or followed.

Specifically,

A) There are no procedures to ensure that the (b) (4) (b) (4) operates as intended and can accurately (b) (4) for various release testing of the raw materials and

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finished products. This includes Tobramycin API, Cromolyn Sodium API, Erythromycin, Sodium Chloride and Artificial Tears. In addition, written procedure, 73-090 Version 01: Determination of (b) (4) Utilizing the (b) (4) and (b) (4) (b) (4):

1. does not include a check for accuracy on the initial (b) (4) (b) (4) used for standardizing the (b) (4) which is used to (b) (4) to ensure the accuracy of the analysis.
2. does not include periodic maintenance. The frequency of replacing the desiccant is not documented and your SOP does not include instruction for how often to do so.

B) The (b) (4) (b) (4) Analyzer was installed at Loop (b) (4) on 01/29/2014 and at Loop (b) (4) on 08/20/2013 of the (b) (4) system which monitors (b) (4) (b) (4) levels, and loop temperatures. SOP 41-048 Version 00: Preventative Maintenance, System Suitability and calibration of the (b) (4) (b) (4) Analyzer is deficient in that the thermometer is not calibrated or verified to ensure that it is accurate. The (b) (4) system suitability only includes a (b) (4) reading and (b) (4)

OBSERVATION 7

Laboratory records are deficient in that they do not include the initials and signature of the second person reviewing the record for accuracy.

Specifically,

A) During a review of (b) (4) Chromatography Data System (CDS), we observed over 200 sequences between 01/01/2017 and 07/01/2018 that contained sample data without an electronic

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reviewer's signature. As per procedure 73-033 Version 09: Use, Maintenance, and Auditing of Quality Control Chemistry Laboratory Notebooks, the QC laboratory notebooks for raw materials, in-process, stability, and finished product testing do (b) (4)

Therefore, an electronic review of (b) (4) CDS is required as stated in section 5.10 of SOP 73-100 version 02: Use of (b) (4) Software for Acquisition, Processing, Reviewing and Archival of Chromatographic Raw Data in the QC Laboratory. However, for the same 200+ sequences mentioned above the reviewer only signed off in the laboratory notebook. For example, a sequence for HPLC analysis of Polyethylene Glycol (PEG) for batch 7A34A 9-month and 12-month stability testing was submitted for review on 05/01/2018 (Sequence completed on 03/09/2018 for both time points) by the analyst and notebook pages were signed off by the reviewer on 05/01/2018 but the (b) (4) CDS is still in "Ready to Review" status as of the current inspection.

Furthermore, we found over 50 additional (b) (4) sequences that were never submitted for electronic review. In one example Lidocaine HCl API batch # (b) (4) was tested for Water Content and Assay on 01/13/17 and 01/17/17, respectively and documented in Laboratory Notebook NB-CH-17-06, pages 3-9. However, the notebook pages were not signed off and the (b) (4) sequence did not have an electronic signature. The analyses were repeated on 08/05/17 and these results were used for Water Content and Assay without explanation or justification.

- B) The Equipment Usage Logbooks are not always reviewed within the (b) (4) procedural requirement and in some cases are missing the "Reviewed by" date requirement. For example, analyses performed on the FTIR on 02/01/18, 02/07/18, 02/15/18, 02/16/18, 02/21/18, 02/22/18, 03/10/18, 04/04/18, 04/27/18, 05/17/18, 05/21/18, and 06/13/18 are missing the "Reviewed by" date. In addition, entries on 02/21/18 and 04/05/18 were reviewed on 04/05/18 and 06/03/18 respectively.

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OBSERVATION 8

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

Specifically,

Multiple test procedures (methods) allow the analyst to adjust the mobile phase components (with additional buffer) to (b) (4). There is no assurance that these mobile phase adjustments made by the analyst during testing will not impact the analysis. For example an analysis of Tobramycin Ophthalmic Solution Batch 7D40 Assay for (b) (4) by HPLC analysis had significant changes to the mobile phase during testing. The analyst used mobile phase that was prepared from the previous batch 7D36 and which already received an additional (b) (4) of buffer. When testing batch 7D40, an additional (b) (4) of buffer was added to the mobile phase. Since the analyst did not note how much mobile phase was remaining when the additional buffer was added, it is unknown what percent of total volume was added to the mobile phase.

PRODUCTION SYSTEM

OBSERVATION 9

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

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A) During the inspection, we observed poor aseptic processing techniques that were previously videotaped at the Class 100 Filling Room #2, Room 1.7.10 on Saturday 07/07/2018.

1. The stainless steel piping connected to the drum filled with Lidocaine Hydrochloride 2% Jelly, USP Sterile, Batch #8G37A, leaking and continuing to spread and create a puddle of viscous product onto the cleanroom floor during the set up and operation of the filling line starting at approximately (b) (4) on 07-07-2018 and ending at approximately (b) (4)
2. Multiple recorded instances of operators walking abruptly in and out of the Class 100 fill room area towards the Class 1000 aseptic corridor throughout the batch run. Operators then proceed to step and move their shoe covered feet directly on top of soiled wipes placed over the floor puddle of viscous leaking product appearing to be Lidocaine Hydrochloride 2% Jelly.
3. At approximately 06:02:28 AM, 07-07-2018, the operator was observed to crouch over and use the filling line machine as support to touch and wipe the bottom of shoe covered foot and then proceeded to touch the filling line machine equipment surfaces without any sanitization in between. The used foot wipe was tossed under the transfer piping and between the can filled with Lidocaine Hydrochloride 2% Jelly, USP Sterile, Batch #8G37A.
4. Instances of an operator using gloved hands that were not sanitized after multiple interventions (including operator moving new can from Class 1000 aseptic corridor into Class 100 area at approximately 07:35:36 am) being used to directly handle the transfer piping of exposed Lidocaine Hydrochloride 2% Jelly, USP Sterile, Batch #8G37A product with gloved hands at 07:44:06 AM, 07-07-2018.

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5. During environmental monitoring (EM), the EM operator was observed to place a white dry wipe over the floor area adjacent to the floor puddle of viscous product, move one side of the EM wheeled cart over the same wipe and then wipe the floor using the bottom of his shoe covered foot at approximately 07:29:53 AM on 07-07-2018. Another operator was then seen to wipe the floor area again between approximately 07:31:28 - 07:31:46 AM, 07-07-2018 prior to EM floor samples being collected within the same floor area at approximately 07:32:06 am, 07-07-2018.

6. At approximately 07:39:38 AM on 07-07-2018, an operator was observed to bend, use the exposed drum transfer piping as support, and crouch over to wipe the bottom of his shoe covered foot. The same operator then proceeded to use the same wipe under his foot to move over the puddle of viscous product in a circular motion between approximately 07:39:40 am and 07:42:35 am and proceeded to wipe the bottom of his foot with a plastic outer covering for wipes at approximately 07:42:41 am. The same operator then proceeded to crumble the plastic in gloved hands and crouched over the can to connect the fittings of exposed pipe and place a new can of Lidocaine jelly product directly over the viscous puddle containing used and soiled wipes without sanitization in between.

7. The transfer piping used between can changes for Lidocaine Hydrochloride 2% Jelly, USP Sterile, Batch #8G37A, remained exposed directly over soiled and used wipes for approximately 10 minutes prior to replacement of new drum. However, can changes were performed within (b) (4) during the aseptic media fill runs without such environment.

B) Non-routine corrective interventions, such as replacing broken parts/materials, performed as part of in-process mechanical repairs during routine filling line operations are not captured within the aseptic media fill program as per SOP 60-023, *Aseptic Media Fills*, Effective Date: 04/21/17 requirement. For example,

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Approximately fifteen (15) incidents of broken pieces being recovered and broken (b) (4) (b) (4) being replaced were logged within the (b) (4) Use Logbook between 02/16/2018 and 08/15/2018. However, mechanical interventions that may last (b) (4) or more for the recovery and repair of broken equipment pieces are not captured within the aseptic media fill program. This includes the following:

1. During the filling of Lidocaine HCL 2% Jelly USP Sterile, Batch #8A22A, Exp: 12/20, Fill Date: 01/16/2018, the line stopped between 11:25 AM and 12:06 PM due to Description of Repair: Broken (b) (4) .
2. During the filling of Erythromycin Ophthalmic Ointment USP 0.5% (1 gram), Batch #8B60, Exp: 01/20, Date: 02/19/2018, the line stopped between 10:20 AM and 10:50 AM due to Description of Repair: (b) (4) Broken.

C) Non-routine filling machine interventions within Class 100 area are not always recorded within batch record occurrence logs as per SOP 61-062, *Filling Room Downtime Documentation Requirements*, Effective Date: 06/03/16 requirement. This includes the following batches with mechanical interventions where there was no mention of the incident within the batch record:

Product	Incident Date	Mechanical Support Daily Use Logbook Comment	Logbook Review Date	Batch Distribution Date and Initial Customer Delivery Date
Erythromycin 1g, Batch #7A23A, Exp:	01/18/17	"Operator reported possibility of particles (shavings) on top of	02/08/2017	02/01/2017 and 03/08/2017

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12/18		(b) (4) (b) (4)		
Gonak 2.5 % Solution, 15 ml, Batch #8G48A, Exp: 06/21	07/17/18	(b) (4)	None	Pending release

In addition, there was no documentation of the continuously leaking transfer piping of viscous clear product onto the cleanroom floor as observed during our review of the previously videotaped filling line run of Lidocaine Hydrochloride 2% Jelly, USP Sterile, Batch 8G37A, Exp: 06/21 (b) (4) filling line # (b) (4) between approximately (b) (4) on 07/07/2018.

OBSERVATION 10

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,

- A) The current equipment cleaning process has not been adequately validated to demonstrate the removal of all drug product residues on the non-dedicated compounding and filling solutions line and the non-dedicated compounding and filling ointments line. There is no data to demonstrate that the cleaning process can remove all the drug product residues from the previous batch. When we reviewed the validation of your cleaning procedures during the inspection, we found that the cleaning validation protocol for the solution and ointment production lines were not even

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approved yet.

- B) There is no evidence to support the (b) (4) dirty hold time and (b) (4) clean hold time being used for non-dedicated equipment (e.g., (b) (4)) on both the liquid and ointment filling lines used in sterile drug products production.

MATERIAL SYSTEM

OBSERVATION 11

Drug product samples are not properly identified.

Specifically,

During our inspectional walkthrough on 08/08/2018, we observed several sample containers labelled with drug product names being stored within undesignated areas without record of receipt, identification of sample disposition, and transfer date to and from location. For example,

- A) At the warehouse located at 69 Veronica Ave, Somerset, NJ, we observed four (4) skids holding numerous white containers of samples with drug product labels. This includes a white container with the following drug product label: Timolol Maleate OS, 0.5%, lot# 6C25, Expiration Date: 02/19, being stored within a skid with the designated sign: "QC Chemistry... To be moved to 68 Veronica." The firm's management personnel present during the walkthrough were unable to provide documented receipt, logged identification, and initial knowledge of the transfer of the

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samples to the warehouse.

- B) At the Analytical Technical Services laboratory located at 68 Veronica Ave, Somerset, NJ, we observed the following drug product samples being stored without a record of receipt, logged identification, disposition and transfer date information for the following QC samples received within the laboratory: Azelastine HCl, Batch #6K90A and Erythromycin Ophthalmic Ointment, USP, Batch # DIN 01912755.

***DATES OF INSPECTION**

7/23/2018(Mon), 7/24/2018(Tue), 7/25/2018(Wed), 7/26/2018(Thu), 7/27/2018(Fri), 7/30/2018(Mon), 7/31/2018(Tue), 8/01/2018(Wed), 8/02/2018(Thu), 8/03/2018(Fri), 8/07/2018(Tue), 8/08/2018(Wed), 8/09/2018(Thu), 8/10/2018(Fri), 8/14/2018(Tue), 8/15/2018(Wed), 8/16/2018(Thu), 8/17/2018(Fri), 8/27/2018(Mon), 8/29/2018(Wed), 8/30/2018(Thu)

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Investigator
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