DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ian M. MacKellar, Site Leader Pfizer Global Supply

FIRM NAME	STREET ADDRESS
Hospira Inc	1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mcpherson, KS 67460-9301	Sterile Drug Manufacture

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

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

Specifically, the completed Daptomycin (b) (4)) Quality Assurance Review / Investigation (PR ID: 2200959, opened 07MAR2018, closed 06NOV2018) related to a (b) (4)) drug product contamination did not include adequate and complete impact and risk assessments as required by SOP-95773 *Manufacturing Investigation Reports*.

OBSERVATION 2

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

Specifically, th (b) (4)S System used to wash, rinse (b) (4) and sterilize components that are used in the manufacturing of aseptically produced products (liquid, lyophilized vials, and carpujects) has not been adequately qualified. There is no assurance that an adequate amount of (b) (4) used to wash components (i.e.: stoppers, plungers and other (b) (4) has been dispensed properly; there is a lack of assurance the proper amount of (b) (4) is dispensed properly as is not

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Still, Investigator Simone E Pitts, National Expert Scott A Golladay, Investigator	X Scott A Golladay Investigator Signed By: Scott A. Golladay -S Date Signed: 01-17-2020 20:47:59	1/17/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

monitored, and at various points during the cycle, the required temperature (i.e. (b) (4)C) is not maintained and/or the temperature falls below the specification limit. The abovementioned parameters were established during the qualification performed on October 25, 1996, Operational Qualification Procedure, QP2840QP and has not been reassessed.

OBSERVATION 3

Adequate exhaust systems or other systems to control contaminants are lacking in areas where air contamination occurs during production.

Specifically, the design of the (b) (4) from the General Processing Area (GPA) Dispensing Room 401(Suite) Grade D is inadequate in that the air handling unit (b) (4) and (b) (4) supporting the GPA dispensing rooms (b) (4) are maintained at the same pressure differential which allows air to cascade from one room to the next before flowing out to the GPA Controlled Not-Classified (CNC) corridor and the warehouse. All raw materials including APIs (potent and non-potent compounds), and excipients are weighed in th (b) (4) before being transferred to production. All products manufactured in GPA and SPA (Special Product Area) receive materials that have been dispensed from (b) (4). Furthermore, as part of the routine cleaning process, (b) (4) and (b) (4) are used in between lots of dispensed materials. Products manufactured in GPA include: Demerol HCl Injection, Retacrit Injection, Vancomycin HCl for Injection and products manufactured in SPA include Hydromorphone HCL Injection, Fentanyl Citrate Injection and Morphine Sulfate Injection.

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Still, Investigator Simone E Pitts, National Expert Scott A Golladay, Investigator	X Scott A Golladay Investigator Signed By: Scott A. Golladay -S Date Signed: 01-17-2020 20:47:59	1/17/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

A. Investigation PR#2668142, opened 10Apr2019, was initiated for a failed glove integrity test performed at the end of a campaign run (b) (4) for Vancomycin Hydrochloride for Injection USP Lot # 030653A and 030553A. The investigation determined that a pin hole present in the shoulder portion of the glove (b) (4) which caused the test to fail. Both product lots were approved and released for distribution as it was deemed no product impact.

B. Investigation PR#4005864, opened 27Jun2019, was initiated for a failed (b) (4) barrier glove test performed during routine preventative maintenance after the production o (b) (4) lots; Hydromorphone HCl Injection (b) (4) Morphine Sulfate Injection (b) (4)), and Diazepam Injection (b) (4) . There were als (b) (4) lots of experimental batches made. The investigation states that "the gloves were not replaced at the time of discovery". No product impact was determined and all associated batches were released.

C. Th (b) (4) aseptic filling line media fill performed during May 29, 2019 is deficient in that the maximum number of personnel described in the protocol was not met. During the inspection, the maximum number of personnel was observed in the aseptic suite of the filling line fo (b) (4) for the majority of the production run of Retacrit (Product Code (b) (4) , Lot #12060DD. The media fill performed on May 29, 2019 for (b) (4) aseptic filling line is not reflective of your firm's current manufacturing processes used to manufacture multiple products such as Vancomycin, Retacrit, and Hydromorphone HCl Injection that require a significant amount of processing time during the aseptic fill.

OBSERVATION 5

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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Still, Investigator Simone E Pitts, National Expert Scott A Golladay, Investigator	X Scott A Golladay Investigator Signed By: Scott A. Golladay -S Date Signed: 01-17-2020 20:47:59	1/17/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

THIS IS A REPEAT OBSERVATION FROM THE AUGUST 2018 INSPECTION.

Specifically,

A. The corrective actions initiated for mold recoveries in your aseptic Grade A and B zones, addressed on the previous inspection, August 2018, FDA 483 Observation 1A, is inadequate, the firm does not have a scientifically sound justification to have released Depacon Valproate Sodium Injection, 500 mg/mL, Lot 83170DD manufactured on 11/20/2017. The firm rejecte (b) (4) lots of drug product with the exception of this one lot due to it being (b) (4) sterilized. There was no written evaluation performed to prove that product impact from mold contamination has been mitigated through (b) (4) l sterilization. The lot was approved for release by Quality on July 5, 2018.

B. On 10/30/2018, an Field Alert McPfar # 2018-132 was initiated for particulate (needle/ metal scuff marks) identified during th (b) (4) retain examination for Hyrdomorphone hydrochloride, Lot # (b) (4) . On June 24, 2019, Biological Product Drug Report (BPDR) MCP 2019-002 was initiated for particulate (needle/ metal scuff marks) identified o (b) (4) Retacrit Lots# (b) (4) The firm's investigation failed to extend the scope across multiple product lines, batches or similar products produced at this site to prevent reoccurrence. These batches were released and approved by Quality.

C. On 11/06/2018, and NDA/ANDA Field Alert Report was initially submitted fo (b) (4) batches of Vancomycin HCl Injection 10g 100mL, Batch 732303A, Expiry 01-01-2019 and Vancomycin HCl Injection 5g 100mL Batch 830103A, Expiry, 08-2019 for (b) (4) observed with embedded material in the glass during the (b) (4) reserve examination. Upon further investigation, 4 units from lot 830103A were identified as having Critical B defects: 1 with a particulate on the internal neck of the unit in product contact; 1 identified with having material in product contact, and 2 were identified as having embedded material encapsulated in the glass and not in product contact. The product contact defects were identified as (b) (4) residue and a (b) (4) powder like residue that was not identified. At the closure of the

investigation, Vancomycin HCl Injection Lot 830103A was approved for released by QA to the market on December 17, 2018 as the firm deemed there was no product impact.

OBSERVATION 6

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

THIS IS A REPEAT OBSERVATION FROM THE AUGUST 2018 INSPECTION.

Specifically,

A. The airflow visualization study, Performance Qualification Final Repor (b) (4) Filling Line Smoke Study PQR0221.10-17-01, is inadequate in that during of loading of the EPA Cart with vials being transported for lyophilization on aseptic filling line (b) (4) turbulence is observed between the interface of the airflow pattern in the Grade A zone, Grade B zone and the operator's removal of the stainless steel tray cover over the partially stoppered vials. The doors on the HEPA cart are opened into the Grade A zone from the Grade B zone and the interface of these two areas creates turbulence as air moves across from left to right in the cart with the downward movement of air in Grade A and the movement of air in the Grade B zone. The report was approved by Quality on 09-29-17.

B. On December 16, 2019 while observing the manufacturing of Hydromorphone Injection Product code (b) (4) , Lot # 12660LL on th (b) (4) Carpuject Line, operators we observed displaying rapid hand gestures, and an operator was observed using their foot to kick a step stool in the Grade A space. Additionally, on December 13, 2019, while observing the manufacturing of Retacrit, Product Code (b) (4) , Lot# 12085DD, on the M6 line, operators were observed leaning over and talking over sterilized items being unwrapped within the aseptic core.

C. There is no assurance the carts observed in the Grade A area with wheels that are difficult to clean are sufficiently cleaned to prevent the transfer of contamination from one area to the next.

D. Specifically, the sterilization qualification studies supporting the CPM (PQR0471.3MAX-18-01), (b) (4) (PQR0471.3Max-17-02, PQR0471.3MAX-18-01, PQR11699.MAX-19-01), (b) (4) (PQR0284.11-19-01) and (b) (4) (PQR0830.00-18-01) componentry processing/preparation workflows do not demonstrate the sterilization o (b) (4) componentry (stoppers, plungers (b) (4) caps) used in Hospira's sterile injectable drug product container closures (cartridges, liquid and lyophilized vials) according to current validation (component inoculum challenge) processes (PR ID: 2439818 (b) (4))) and cGMPs.

E. We observed several poor aseptic practices within your Grade A zones i (b) (4) an (b) (4) processing fill lines on or about 12/ 11/ 2019:

1. Operator were observed placing the wrapped filling manifold on th (b) (4) filling line, cutting the wrapping with sterile scissors, and then removing the wrapping while it was under the Grade A critical zone.
2. I observed no continuous particle monitoring while operators were making aseptic connections in th (b) (4) cabinet Grade A zone during the production batch of Retarit Lot # 12085DD (Product Cod (b) (4)) on asepti (b) (4) filling line.
3. Operators were observed performin (b) (4) set up by working over opened product (b) (4) prior to the actual production run. Additionally, the firm's Quality on the Production Floor was not able to see the critical operations occurring on the floor.
4. The produc (b) (4) was observed bein (b) (4) (b) (4)). Furthermore, the (b) (4) was observed being assembled using multiple attempts to (b) (4) within the aseptic core. This may compromise the integrity of th (b) (4) that lead to leaks during the aseptic fill.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

OBSERVATION 7

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically,

A. On August 21, 2019, an NDA Field- Alert Report McPfar# 2019-043 was initiated for the recovery of 2 species of mold (Cladsporium species and Sarocladium terricola) equaling 62 cfu from the multi-product aseptic filling lin (b) (4) Grade A zone where lyophilized product is transferred to the lyophilizer trayer. Furthermore, 6 cfu of bacterial colonies (Brachybacterium rhamnosum) were recovered from the Grade A zone from the same settle plate. In addition, on August 16, 2019, a recovery of 2 cfu of mold colonies (Aspergillus species) were isolated from the personnel/material Grade B (b) (4) Grade A/B aseptic area.

The mold and bacteria recoveries were identified in the Grade A aseptic zone where lyophilized and sterile solutions are produced. The firm has failed to identify product associated within the filed NDA Field- Alert. However, according to PR#4138900, there wer (b) (4) lots manufactured during the time of the event and (b) (4) lots were released into market. Excursions were due to a missed cleaning and room pressure excursions.

B. On 12/02/2018, an NDA Field-Alert Report McPfar# 2019-150 was initiated for the recovery of 2 species of mold (Tritirachium oryae and Asperigillus sydowii) equaling 14 cfu from the multi-product aseptic filling lin (b) (4) Grade A zone where the aseptic solution connection is performed. Investigation PR# 2514531 determined that there was no impact to Plazomicin Lot# 951003F and released the batch. Root causes and corrective actions are not robust to mitigate risk and re-

occurrence.

C. On 08/06/2019, an ANDA Field-Alert Report McPfar #2019-037 was initiated for the recovery of 1 cfu of mold growth found on a viable passive air site in the Grade A(b) (4) isolator on July 26, 2019. Investigation PR#4097952 rejected Glatiramer Acetate Injection 20 mg/mL, Lot 070653F. However, the investigation failed to implement an effective CAPA to control contamination within the aseptic isolator barrier Grade A zone.

D. Investigation PR# 4146395 failed to adequately address the air reversal excursions affecting Grade A/ B (b) (4)(room 338A) from the Grade D area supporting the asepti (b) (4)filling line. The room air pressure increases when Grade D room doors are open at the same time as the Grade B doors leading to the asepti (b) (4)filling area. Corrective actions implemented did not mitigate future occurrences

E. On 12/22/2018, Field Alert McPfar 2018-169 was initiated for 23 cfu of mold contamination detected inside a HEPA car (b) (4), used to transport aseptic product from th (b) (4)filling line. The field alert did not indicate that Vancomycin Hydrochloride for Injection, Lot 96170DD was implicated and later rejected as a batch disposition. Furthermore, the the Field Alert and CAPA PR#2543245, failed to evaluate the (b) (4)sanitation process of the HEPA carts from the dates of closure, June 2019, to address the interim process that will be used to mitigate risk. HEPA Carts are still being (b) (4) sanitized to be reintroduced back into the clean rooms.

F. On 01/23/2019, Field Alert Report McPfar 2019-006 was initiated in response to investigation PR#4322158 initiated for 1cfu for a Class 1, Grade A personnel that was working in the Grade A zone o (b) (4)filling line. The investigation identifies the cause of the mold species being due to gowning. However, the firm has failed to implement appropriate corrective actions that prevent mold excursions identified on Class 1 employee working inside a Grade A zone. All product batches associated with this personnel excursion were released for distribution.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

G. The firm has not initiated an overall effective corrective action plan to mitigate the re-occurrence of bacterial and/or mold colonies isolated from points throughout the aseptic manufacturing suites and supporting areas. Since the last inspection in August 2018, the firm continues to recover bacterial and/or mold isolates from critical zones Grade A and B, supporting areas, and Class 1 personnel.

OBSERVATION 8

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.

Specifically, your overall endotoxin control strategy is inadequate and does not meet the requirements established in SOP-9605 (b) (4) *Monitoring Program* and cGMPs.

A. There is no direct/formal confirmation of endotoxin sample hold time during the manufacture of the Nivestim™ biologic drug product, including but not limited to bulk samples from lot 01320DD, during compounding (BPR – Compounding (b) (4)) and unit samples from vial filling (BPR – Filling (b) (4) operations, ensuring conformance to time limitations established during the (b) (4) validation (PQR0056.00-16-08).

B. The (b) (4) systems supporting the CPM (CARPUJECT™) componentry workflow fail to achieve your targeted (b) (4) reduction of endotoxin. The performance qualifications report minimum endotoxin log reductions o (b) (4) an (b) (4) glass cartridge, PQR0254.00-19-02 (b) (4) PQR0254.00-19-02 (b) (4)), 2.9 (plunger/rubber component, PQR0130.20-19-07) and 1.8 (b) (4) [cap, PQR0130.20-19-06). The routine (b) (4) monitoring program for componentry (SOP-96954 *Sampling of Manufacturing and Packaging Components),* in absence of (b) (4) eduction in endotoxin, does not employ a statistically valid/acceptable sampling plan. For example (b) (4) glass cartridges (SOP-96954) will be assessed for endotoxin from (b) (4) (b) (4) batch which routinely exceeds (b) (4) units (b) (4) ,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Still, Investigator Simone E Pitts, National Expert Scott A Golladay, Investigator	X Scott A Golladay Investigator Signed By: Scott A. Golladay -S Date Signed: 01-17-2020 20:47:59	1/17/2020

(b) (4)).

C. The Morphine Sulfate endotoxin specifications for componentry (SOP-96054), raw materials/excipient (b) (4)) and drug substance (b) (4) do not ensure the finished drug product will meet specification (b) (4) . If the drug substance, raw materials and componentry approach the specification limits for endotoxin, the combined endotoxin load will exceed the drug product specification. An endotoxin value in excess of the drug product specification may not be detected through finished drug product testing due to the very limited/inadequate sampling plan (e.g (b) (4) out of approximately (b) (4) units for drug product, Contro (b) (4) , (b) (4)).

D. The endotoxin control strategy does not include an evaluation (e.g. (b) (4) an (b) (4)) of the effect of hold time on the ability to detect endotoxin in all applicable sterile drug products (in-process / bulk and finished). Further, you have not demonstrated your ability to detect endotoxin over your specified sample storage time and conditions in complex formulations/matrices including but not limited to solubilization and/or stabilization agents.

OBSERVATION 9

Master production and control records lack complete manufacturing and control instructions and precautions to be followed.

Specifically, during the manufacture of Hydromorphone (lot 12660LL) in room 219A (Grade D) on 12/17/2019, I observed a (b) (4) repeatedly used for th (b) (4) transfer o (b) (4) solution from (b) (4) . Th (b) (4) containing residual solution, is kept uncovered and directly on the floor throughout the manufacturing process. The approved Master

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

Production Record (MPR (b) (4)) and associated operating procedure (SOP-95285(17.0)) for th (b) (4) (CARPUJECT™ and iSecure™ Syringe Systems) production line, including but not limited to the Batch Production Record (BPR) for the Hydromorphone (Product Code (b) (4) (b) (4) .) sterile injectable drug product, do not provide procedures or training for use of th (b) (4) for the (b) (4) solution transfer and precautionary safeguards to adequately protect from particulate contamination afte (b) (4) washing.

OBSERVATION 10

Your examination and testing of samples did not assure that the drug product and in-process material conformed to specifications.

Specifically, you (b) (4) visual inspection processes are inadequate for the following:

A. On 1/14/2020, I observed the Heparin (Carpuject Syringe System) sterile drug product (product code (b) (4) , lot 12565LL) bein (b) (4) inspected (defect classification) after defect detection using the (b) (4) inspection system in room 677 (b) (4) . I observed, during (b) (4) visual inspection for defect classification (b) (4) and (b) (4)) that failed to undergo a complet (b) (4) visual inspection sequence ensuring the assessment of all possible defect classifications and the correct criticality assignment, including the requirement to identify the most critical defect according to SOP-96243 *Carpuject Visual Inspection and Defect Library*. This procedural failure effects the development of visual inspection defect classification limits (SOP-96222 *Defect Limit and Monitoring Procedure*) and tracking (SOP-95147 *Defect Tracking*), compromising statistical process

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Still, Investigator Simone E Pitts, National Expert Scott A Golladay, Investigator	X Scott A Golladay Investigator Signed By: Scott A. Golladay -S Date Signed: 01-17-2020 20:47:59	1/17/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/9/2019-1/17/2020* FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ian M. MacKellar, Site Leader Pfizer Global Supply	
FIRM NAME Hospira Inc	STREET ADDRESS 1776 Centennial Dr
CITY, STATE, ZIP CODE, COUNTRY Mcpherson, KS 67460-9301	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacture

control.

B. On 1/14/2020, I observed liquid vials of the sterile Hydromorphone (controlled substance) drug product (product code (b) (4) lot 120653A) bein (b) (4) inspected for defect classification after initial defect detection using th (b) (4) an (b) (4) (b) (4) in room 615 (b) (4). The inspector's defect criticality assignment trays are (b) (4) impeding individualized a untability, nonconformance assessment, supervisor oversight/review, corrective training and controlled substance tracking.

***DATES OF INSPECTION**

12/09/2019(Mon), 12/10/2019(Tue), 12/11/2019(Wed), 12/12/2019(Thu), 12/13/2019(Fri), 12/16/2019(Mon), 12/17/2019(Tue), 12/18/2019(Wed), 12/19/2019(Thu), 12/20/2019(Fri), 1/13/2020(Mon), 1/14/2020(Tue), 1/15/2020(Wed), 1/16/2020(Thu), 1/17/2020(Fri)

X Simone E Pitts
National Expert
Signed By: Simone E. Pitts -S
Date Signed: 01-17-2020 20:48:56

X Jazmine N Still
Investigator
Signed By: 2001954135
Date Signed: 01-17-2020 20:49:27

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Still, Investigator Simone E Pitts, National Expert Scott A Golladay, Investigator	X Scott A Golladay Investigator Signed By: Scott A. Golladay -S Date Signed: 01-17-2020 20:47:59	1/17/2020

The obser Ftions of objection ble conditions Fnd pr ctices listed on the front of this form F re reported: F

1. Pursu nt to Section 704(b) of the eder l ood, Drug Fnd Cosmetic Act, or F
2. To ssist firms inspected in complying with the Acts nd regul tions enforced by the F ood Fnd Drug Administr tion. F

Section 704(b) of the eder l ood, Drug, nd Cosmetic Act (21 USC 374(b)) pro ides: F

"Upon completion of ny such inspection of F f ctory, w rehouse, consulting F l bor tory, or other est blishment, Fnd prior to le Fing the premises, the officer or F employee m akiFng the inspection sh ll gi e to the owner, oper tor, or gent in ch rge F report in writing setting forth ny conditions or pr ctices obser ed by him which, in his F judgment, indic te th t ny food, drug, de ice, or cosmetic in such est blishment (1) F consists in whole or in p rt of ny filthy, putrid, or decomposed subst nce, or (2) h s F been prep red, p cked, or held under ins nit ry conditions whereby it m ayFh Fe become F cont min ted with filth, or whereby it m ayFh Fe been rendered injurious to he lth. A copy F of such report sh ll be sent promptly to the Secret ry." F