DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	9/10/2018-10/12/2018* FEI NUMBER 3014184709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel C. Py, CEO & Chairman	
FIRM NAME	**STREET ADDRESS**
Intact Pharmaceuticals LLC	201 Housatonic Ave
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
New Milford, CT 06776-5540	Outsourcing Facility

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

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, facilities and equipment used for the aseptic filling of 0.9% Sodium Chloride Solution for Injection lack controls designed to consistently provide sterility assurance for the drug product. You do not demonstrate adequate control of the environment in the (b) (4) and over the (b) (4) (b) (4) system to ensure that (b) (4) are protected from contamination during drug product filling operations. For example:

1. Your filling area is not ISO 5 classified and the surrounding area is not classified to ISO 7 standards. Instead, you operate the filling system in a controlled, non-classified (CNC) environment.

2. HEPA filters mounted in the top of the (b) (4) located over the filling zone are not certified by criteria to include leak testing nor are they periodically tested for leaks. The Cleanroom Certification Report dated 02/23/2018 only reported air velocity measurements 3-6 inches from the filter face and calculated airflow volume for the HEPA filters in the (b) (4) Furthermore, your firm has not established specifications for air velocity and the results were not reviewed or approved by your Quality Unit.

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	Edmund F Mrak, Investigator Djamila Harouaka, FDA Center Employee or Employee of Other Federal Agencies	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 10-12-2018 15:42:59	10/12/2018

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3. You did not directly test airflow patterns within the (b) (4) to visualize and evaluate air flow patterns particularly in the most critical area around the (b) (4) (b) (4) under filling conditions.

4. Your air flow pattern study performed 06/01/2018 demonstrated turbulent air flow in the (b) (4) (b) (4) area. The demonstrated airflow would not be expected to provide first pass air over the (b) (4) during preparation for (b) (4) and filling. Additionally, your air flow pattern studies were not reviewed and evaluated by your Quality Unit and other responsible individuals in your firm.

   a. You did not have a test protocol or other documentation to guide testing requirements for evaluation of airflow over the (b) (4) handling area and (b) (4) system conducted on 06/01/2018 by your contractor. Furthermore, you did not establish requirements for the operating conditions to be evaluated and any meaningful acceptance criteria for evaluation of critical attributes for airflow over the (b) (4) handling area and (b) (4) system.

5. You do not demonstrate expected performance over the lifecycle of HEPA filters fixed over the (b) (4) and (b) (4) and (b) (4) said to provide HEPA filtered air to minimize particulate contact with (b) (4).
   a. HEPA filters mounted in the (b) (4) over the (b) (4) (b) (4) and (b) (4) and (b) (4) are not certified by criteria to include leak testing nor are they periodically tested for leaks.
   b. You lack a decommissioning plan to include HEPA filter evaluation prior to removal of the (b) (4) replaced HEPA filter component of filter/fan units fixed over the (b) (4) (b) (4) and (b) (4) and (b) (4)

6. The (b) (4) said to reduce the risk of operators and particulate contact with (b) (4) to filling (b) (4) was cracked and crazed directly over the (b) (4) around HEPA filter / fan mounting bolts.

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7. Ceiling mounted HEPA filters in the Filling Room (IP-115) (b) (4) Room (IP-117) (b) (4) Room (IP-119), and Compounding Room including ISO 8 (b) (4) (IP-113) are not certified by criteria to include leak testing nor are they periodically tested for leaks. Furthermore, you have not established specifications for acceptance of HEPA filter performance or for particle counts in CNC areas and test results are not reviewed or approved by your Quality Unit.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm does not require or perform routine environmental monitoring of areas associated with the production of 0.9% Sodium Chloride Solution for Injection. For example:

1. Your firm does not perform routine environmental monitoring to include total particle counts, surface and airborne viable sampling inside the (b) (4) or in the interior of the (b) where the filling operation occurs.
2. Your firm does not perform routine environmental monitoring to include total particle counts, surface and airborne viable sampling in the (b) (4) where the sterile (b) (4)
3. Your firm does not perform routine monitoring of viable particles (surface and air) inside of the ISO 8 (b) (4) used for formulation.
4. Your firm does not perform routine environmental monitoring in the rooms associated with the production of 0.9% Sodium Chloride Solution for Injection including the Filling Room, Formulation Room, Gowning Room, and (b) (4) and (b) (4) areas.
5. Your firm does not monitor differential pressure between controlled non-classified (CNC) areas and the surrounding non-classified (NC) areas.

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OBSERVATION 3

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

Specifically:

1. (b) (4) was not adequately validated. The test results are used to release (b) (4)). For example: Test results were reported in the Lot Design Verification Report and Certificates of Quality for the release of (b) (4) used to manufacture 0.9% Sodium Chloride for Injection 0.9% Lot # 0918-02 and the process validation Lots (b) (4) respectively. Test results were also reported in the Certificates of Analyses used to release (b) (4) (b) (4) prior to single use final fill kit assembly (pre-sterilization).

   The following deficiencies in your validation of the (b) (4) maintenance and control of test equipment were observed:

   a. (b) (4) . There is no dedicated equipment log; no preventive maintenance program; control parameters for maintaining the (b) (4) microbial challenge concentration during inoculation were posted on the (b) (4) on an uncontrolled hand-written note; and you did not validate the test method by directly demonstrating that the target exposure or number of organisms applied to test (b) (4)

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b. A deviation reported in your Validation Protocol PRO-0003, Revision A, effective date: 22 June 2016 revealed that a (b) (4) was used instead of a (b) (4) (b) (4) during validation of (b) (4) You did not evaluate the impact of using the (b) (4) on the validation status of (b) (4) when using the (b) (4) specified for commercial production of Sodium Chloride for Injection 0.9%, 75ml.

2. Media fills used to validate the production of 0.9% Sodium Chloride Solution for Injection, 75ml were deficient because media fill batch records did not reconcile the total number of units that were filled, rejected, incubated, and evaluated. There is no assurance that all integral filled units were incubated and evaluated during the media fills.

3. The (b) (4) and the (b) (4) said to verify the (b) (4) used for process validation lots (b) (4) (b) (4) are deficient as follows:

   a. Test data reported for validation lots (b) (4) had no indication of a pass/fail result or other assessment criteria on the forms used to report the data.

   b. You did not review or evaluate the calibration report generated by the calibration vendor for the (b) (4) used to perform (b) (4) (b) (4) and (b) (4) Furthermore, you have not established acceptance criteria for the instrument calibration.

OBSERVATION 4

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically, you have not established effective procedures and practices to reduce microbiological challenge during the production of Sodium Chloride for Injection 0.9%, 75ml.

1. During formulation of batch # F0918-01 on 09/12/2018, we observed an operator contact the interior (b) (4) with non-sterile gloved hands. The operator repeatedly touched the inside (b) (4) During formulation the operator also touched the (b) (4) with non-sterile gloves and sleeves. (b) (4) was replaced (b) (4) The bulk formulation may be held for up to (b) (4)

2. We observed an operator hold a sterilized (b) (4) near her face prior to use. The skin of the operator's forehead and cheeks was exposed. The (b) (4) was used to (b) (4) (b) (4) during production of batch # F0918-01 on 09/12/2018.

3. The (b) (4) inside the ISO 8 (b) (4) (IP-113A) approximately 5 feet under a metal frame and HEPA filter diffuser panel that appeared to be chipped, deteriorated, or damaged. There was a floor drain located inside IP-113A.

4. During the filling of batch # 0918-02 on 09/13/2018, the loading operator's non-sterile gloved hands were observed to contact (b) (4) during (b) (4) and preparation for (b) (4)

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5. (b) (4) [redacted], operators were observed working with non-sterile gloved hands and non-sterile sleeved arms between the HEPA filter and (b) (4) [redacted] The non-sterile gloves and sleeves were in direct contact with (b) (4) equipment above and adjacent to the filling station during assembly.

6. (b) (4) sanitizer observed inside the CNC (b) (4) room (IP-117) was not labeled sterile and is not released by the Quality System or evaluated by the Quality Unit before use. Operators use the (b) (4) hand sanitizer to sanitize their non-sterile gloves before inspecting and (b) (4) (b) (4) [redacted]

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, deficiencies were noted with frequency of cleaning, the wipes used for cleaning, and the contact times applied to disinfect CNC areas used for production of 0.9% Sodium Chloride for Injection. For example:

1. The sporicidal agent, (b) (4) [redacted] is used with a (b) (4) minute contact time. However, the manufacturer's recommended contact time is (b) (4) minutes for sporicidal activity.

2. Surfaces inside the (b) (4) [redacted]; interior of the (b) (4) [redacted] and the (b) (4) [redacted] station in the (b) (4) area are not periodically sanitized with a sporicidal agent. Sanitization of these areas is performed only with (b) (4) [redacted] and non-sterile cleanroom wipes. Sterilized (b) (4) [redacted] are placed directly on the surface of the (b) (4) [redacted] station table.

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3. Vinyl curtains separating the (b) (4) areas are repeatedly contacted by the non-sterile gloves and gowns of operators passing through them during production. The curtains are cleaned (b) (4) with non-sterile wipes and sterile (b) (4)

4. Personnel are allowed to enter CNC production areas with street clothes when there are no production activities. You have not established procedures to ensure that the areas are re-cleaned and sanitized to establish expected environmental conditions before resuming production of drug product in affected areas.

OBSERVATION 6

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

Specifically, deficiencies in oversight provided by the Quality Unit and failure to follow established procedures were observed as follows:

1. The Quality Unit did not ensure material status assignment and disposition procedures were followed and failed to ensure that material was rejected and/or destroyed in a timely manner. Bulk 0.9% Sodium Chloride Solution, Batch # F050518, manufactured on 06/21/2018 was held in Quarantine when the maximum allowed hold time for the bulk solution is (b) (4)

2. The Quality Unit does not consistently review production batch records for correctness and completeness and/or approve batches for release:

    a. The batch record for 0.9% Sodium Chloride Solution for Injection process validation fill lot # (b) (4) manufactured 19 April 2018 – 23 April 2018, was not reviewed or approved by the Quality Unit.

    b. The batch record for process validation formulation lot# (b) (4) was approved by the Quality Unit on 19 April 2018 before review was documented by the supervising Pharmacist on 2 May 2018.

3. The Quality Unit does not ensure quality records such as change control records or deviation investigations are completed, reviewed and approved. For example:

    a. Change control record CCR-0009, dated 10/09/2017, described the installation of (b) (4)

(b) (4) . The change was approved by Quality Assurance on 10/10/2017 and by the Director, Quality and Regulatory on 10/09/2017. However, the record does not contain approvals following implementation of the change, an assessment of the effectiveness of the change, and the change control record was not closed.

b. Change control record CCR-0011, dated 01/22/2018, described the (b) (4) and there is no indication that the Quality Unit reviewed and approved the change. The change control record does not describe the modification to the (b) (4) or whether (b) (4) The change control assignment log indicates that the work was completed, although no date is given.

c. Change control record CCR-0015, dated 03/29/2018, describes (b) (4) The change control record impact assessment, implementation plan, and QA approval are blank and there is no indication that the Quality Unit reviewed and approved the change.

d. Your Quality Unit did not ensure that bioburden testing of samples for the formulation process validation batches (b) (4) were performed using a validated test method. Initial release criteria for the packaged finished product given in INS-IPH20030-IPHARMA, Revision B, includes bioburden testing of the bulk formulation. The process validation batches were used to establish the (b) (4) hold time for the bioburden controlled bulk Sodium Chloride Solution.

4. Your Quality Unit failed to ensure that manufacturing component vendor controls and release requirements were appropriate and met before component use in drug product production. For example:

a. You have not established specific and appropriate requirements for facility classification and production conditions for your component manufacturer to prevent objectionable contamination of your primary container/closures used for 0.9% Sodium Chloride Solution for Injection, 75ml. Your component Specification, Doc #: SPC-100583-IPHARMA, Effective: 08/08/2017, for (b) (4)

(b) (4) acceptance criteria requires the vendor Certificate of Conformity (b) (4)

b. The Certificate of Conformity presented for the release disposition of (b) (4) did not include any statement to certify the environment for manufacture of (b) (4) and you released the lot on 09/05/2018 despite missing this information necessary to evaluate the component according to current acceptance criteria.

c. You approved the manufacturer/supplier of (b) (4), despite an incomplete Supplier Approval Form, Approval Dated: 02/28/2017.

d. Your Component Specification, Doc #: SPC-100622-IPHARMA, Approved: 09/08/2017 for the (b) (4) which includes the (b) (4) requirements for facility classification and production conditions to prevent objectionable contamination during the assembly of the kit by the component manufacturer.

e. You approved the manufacturer/supplier of the (b) (4), despite an incomplete Supplier Approval Form, Approval Dated: 09/08/2016. The Review Summary indicates that "Requirements have been partially met" however there are no written comments or rationale to support approval of the supplier.

OBSERVATION 7

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.

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. Specifically,

1. You failed to initiate investigations to include the root cause of failed Media Fill Lots (b) (4) documented in test reports IPTRF17-0049, IPTRF17-0050, IPTRF17-0051, and IPTRF17-0054. Furthermore, you did not document corrective actions or any other changes implemented in the filling process, equipment, or components to achieve subsequent successful aseptic simulations.

2. Deviation record DR-0006, dated 12/13/2017, describes Media Fill Lot (b) (4) failure reported in test report IPTRF17-0007. The deviation record does not describe the number of failed units. The record indicates a CAPA was required, but no additional information is included. The incomplete record was approved by the Quality Unit on 12/13/2017.

3. A failure of Media Fill Lot (b) (4) was recorded on 12/20/2017, but no deviation record was created to capture or investigate this event.

4. You did not investigate the failure of (b) (4) in November 2017 during a media fill or the needle failures observed for media fill lot (b) (4) in December 2017.

OBSERVATION 8

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically:

1. Personnel don non-sterile gowning components for production of sterile 0.9% sodium chloride for injection, 75ml. Personnel don non-sterile bouffant caps, beard covers (if necessary), face masks, coveralls, safety glasses, designated plant shoes, and non-sterile gloves in room IP-111, which is maintained as a CNC environment. The skin of the forehead and cheeks remain exposed. Non-sterile sleeves are donned by operators working within the ISO 8 (b) (4) during

formulation and in the Filling Room (IP-115) during the setup of the (b) (4)

2. On 09/12/2018, manufacturing personnel were observed wearing non-sterile gowning including gloves, sleeves, and coveralls to formulate bulk 0.9% sodium chloride for injection, Batch # F0918-01, inside of the ISO 8 (b) (4) located in room IP-113.

3. On 09/13/2018, manufacturing personnel were observed wearing non-sterile gloves, sleeves, and coveralls to set up the (b) (4) for production of 0.9% sodium chloride for injection, lot number 0918-02.

OBSERVATION 9

Individuals responsible for supervising the manufacture and processing of a drug product lack the training to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

The Pharmacist that supervises the formulation and filling of sterile 0.9% Sodium Chloride Solution for Injection was not trained in all relevant procedures. For example:

a. On 09/12/2018, while supervising the formulation of 0.9% Sodium Chloride Solution Batch# F0918-01, the pharmacist's coverall appeared to be partially unzipped. This pharmacist (b) (6) was not trained to follow your firm's gowning procedure, SOP-100354-IPHARM, Revision B, effective date 06/21/2018, titled Manufacturing Area Gowning until 09/12/2018.

b. There is no documented evidence that a trained pharmacist supervised the production of the process validation batches for 0.9% Sodium Chloride Solution for Injection in April 2018. Pharmacist (b) (6) approved the batch records for validation batches (b) (4) (b) (4) Pharmacist (b) (6) was trained on 05/02/2018 on the Master Batch Record – Sodium

Chloride for Injection, 0.9% -(b) (4) NaCl, OPR-100795-IPHARMA, Revision A, effective date 05/09/2017.

c. Pharmacist (b) (6) supervised the formulation of 0.9% Sodium Chloride Solution Batch #F0918-01 on 09/12/2018. He was trained a day later on 09/13/2018 on the updated revision of the Master Batch Record – Sodium Chloride for Injection, 0.9% -(b) (4) NaCl, OPR-100795-IPHARMA, Revision C, effective date 09/03/2018.

OBSERVATION 10

Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically:

1. (b) (4) was not calibrated, and you do not have an equipment use and maintenance log for (b) (4) and there is no preventive maintenance (PM) and calibration program established to ensure expected performance of the system and accurate test results. Integrated device components of the (b) (4) for measuring and controlling (b) (4) (b) (4) are not calibrated or included in any calibration quality system.

   Additionally, ancillary equipment used to support the test method was not calibrated as follows:

   a. Calibration of the temperature control for the incubator said to be used to incubate (b) (4) (b) (4) (b) (4) expired 05/05/2018 and a

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(b) (4) expired Oct 2017. The equipment was last used in support of testing for release of (b) (4) on 08/17-30/2018.

b. Calibration of the temperature control for the freezer used to store (b) (4) expired 05/05/2018. The equipment was last used in support of testing for release of (b) (4) on 08/17-30/2018.

c. The temperature control for the freezer used to hold working cultures used in the (b) (4) was not calibrated. The equipment was last used in support of testing for release of (b) (4) on 08/17-30/2018.

OBSERVATION 11

Equipment surfaces that contact drug products are reactive, additive or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Specifically:

You did not perform drug product compatibility studies for materials of construction of the (b) (4) (b) (4) which includes the (b) (4) (b) (4) (b) (4)

*DATES OF INSPECTION

9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/13/2018(Thu), 9/14/2018(Fri), 10/11/2018(Thu), 10/12/2018(Fri)

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