

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

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 5/20/2019-6/20/2019*
	FEI NUMBER 3011319445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ponswamy Rajalingam, President & Owner

FIRM NAME Hybrid Pharma LLC	STREET ADDRESS 1015 W Newport Center Dr Ste 106A
CITY, STATE, ZIP CODE, COUNTRY Deerfield Beach, FL 33442-7707	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

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

Specifically,

1. Media fills conducted between 9/23/16 and 3/15/19 were not performed that closely simulated aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. This is a repeat observation.
2. Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing. You have no assurance that the endotoxin level of your intrathecal drug products are safe since you do not have any endotoxin data, and your firm does not perform endotoxin testing of finished product. These drug products are made using nonsterile starting material.
3. HEPA filter first-air was intermittently blocked by the aseptic techniques of the sterile technician during the (b) (4) of Procaine 20mg/ml, lot 190524A as observed on 5/24/2019. The technician's forearm passed over the filled vials as they were filled from (b) (4)
4. The technician's hand washing and gowning procedures observed during the production of Procaine 20mg/ml lot 190524A were deficient in that:
 - Hand washing techniques do not include the use of a nailbrush to effectively remove debris

AMENDMENT 1

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from underneath the nail bed.

- Portions of the technician's sterile coveralls touched the flooring within the ISO 8 preparation room while donning.
- Nonsterile goggles are worn.

OBSERVATION 2

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

Specifically,

- a. On 5/20/19 a brown discoloration was observed on the HEPA filter inside the ISO 5 hood

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located in ISO 7 Buffer Room (b) (4). The same discoloration was also observed on an inoperable HEPA filter within this buffer room, located to the left of the ISO 5 hood. This filter has been inoperable for an unknown length of time.

- b. On 5/20/19 a brown discoloration was observed on the interior wall above the doorway within ISO 7 Buffer Room (b) (4). This buffer room supports the aseptic filling operations of hazardous compounds within its ISO 5 BSC hood.
- c. The efficacy studies performed on 11/1/2018, and 2/4/2019 to demonstrate that (b) (4) disinfectant and the (b) (4) sporicidal solution used to disinfect work surfaces, floors, walls and ceilings within your cleanrooms was performed using unidentified locations outside of the cleanroom. The study is not well-defined and does not represent actual use.

This is a repeat observation.

OBSERVATION 3

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

Specifically,

- 1. Smoke studies are not properly conducted under dynamic conditions to assure uniform and unilateral HEPA air controls within ISO 5 hoods and during the transfer of (b) (4) vials from an ISO 5 zone to the (b) (4).
- 2. Non-viable monitoring within the ISO 7 buffer rooms is not continuously performed during routine production. A (b) (4) sample is collected prior to vial filling.

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OBSERVATION 4

Aseptic processing areas are deficient in that floors and ceilings are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

1. The flooring within ISO 7 Buffer Room (b) (4) to include underneath the ISO 5 BSC hood contained within this room is constructed of a vinyl tile-like surface with embedded grooves which are not easily cleanable.
2. There were several loose ceiling tiles observed above the ISO 5 hoods within your ISO 7 Buffer Rooms (b) (4)

OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

The following deficiencies were observed in the room certification report # A2915396 dated July 30 2018

1. HEPA filter leak testing within the ISO 8 preparation room was not completed
2. HEPA filter leak testing within the ISO 7 buffer rooms were not completed

The following deficiencies were observed in the room certification report# A3083463 dated January 25 2019:

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1. HEPA filter leak testing within the ISO 8 preparation room was not completed
2. HEPA filter testing within the ISO 7 buffer room (BR) was not completed

OBSERVATION 6

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

1. The (b) (4) (b) (4) parameters used to (b) (4) your HCG drug product formulations have not been validated to ensure such parameters are adequate.
2. (b) (4) sterilization (b) (4) parameters used to (b) (4) the following drug products have not been validated:
 - Pyridoxine Hydrochloride 100mg/ml - (b) (4)
 - Calcium Gluconate 10% Inj - (b) (4)
 - Cyanocobalamin 100mcg/ml - (b) (4)

OBSERVATION 7

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

1. The procedures utilized in validating the HPLC, UV Spectrometry, and Titrimetric methods used for potency analysis of finished drug products are not properly designed such that all data generated can be properly assessed to establish that such methods consistently meets standards of accuracy and reliability.

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2. Routine finished product release testing records do not include a complete record of all data obtained during the analysis to include (but not limited to):
 - a. System suitability determinations
 - b. Standards and sample preparations
 - c. All calculations performed during the analysis

OBSERVATION 8

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

Specifically,

1. There is no formal written stability program to assess all stability characteristics of finished drug products.
2. Stability studies performed to establish a six-month beyond use date for your finished products are based on trial batches and not on actual finished product lots.

This is a repeat observation

OBSERVATION 9

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

OBSERVATION 10

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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Specifically,

1. There are no records documenting the training provided to the staff pharmacist in her areas of responsibility.
2. Training records are not maintained covering all responsibilities and duties assigned to technicians in the production, processing, and packaging of drug products.
3. Visual inspection training procedures and records are not documented for technicians performing visual inspections of finished product to detect defects or product contamination.
4. There is no established frequency or documentation of GMP training provided to employees.

OBSERVATION 11

The labels of your outsourcing facility's drug products are deficient.

Specifically,

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

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The statement "This is a compounded drug"

Examples of your drug product labels that do not contain this information:

- Glutathione 100mg/mL
- Morphine 10mg/mL / Bupivacaine HCl 10mg/mL, PF
- Butt Balm 30g
- Ascorbic Acid 500mg/mL
- B6-Fusion 100mg/mL

This is a repeat observation.

***DATES OF INSPECTION**

5/20/2019(Mon), 5/21/2019(Tue), 5/22/2019(Wed), 5/23/2019(Thu), 5/24/2019(Fri), 5/28/2019(Tue), 5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/20/2019(Thu)

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