

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov		DATE(S) OF INSPECTION 7/27/2021-9/3/2021*
		FEI NUMBER 3011319445
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ponswamy Rajalingam, Owner & President		
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

Investigations of an unexplained discrepancy 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.

Your firm does not conduct adequate investigations of unexplained events or occurrences. Specifically,

- A. During the 100% visual inspection of Magnesium Chloride 200 mg/mL, Lot (b) (4), the operator found 5 of (b) (4) vials containing particles. Possible sources of contamination included fibers from gowning sleeves and dust from carrying bins, resulting in a change of gowning procedures (b) (4), wiping of bins, and rewashing vials. However, the investigation was not comprehensive in that it did not consider other sources of contamination such as the bulk drug, personnel contribution, or the routine movement of vials. Additionally, the investigation did not extend to other batches.
- B. A complaint of particles found in 9 vials of Magnesium Chloride 200 mg/mL, Lot (b) (4), BUD 10/17/20, was received on 08/21/2020. You contacted recipients of Lot (b) (4) and relied on customer testimony to determine that other vials contained no particles. According to the CAPA investigation, you reviewed retain samples "at the time of complaint" and found no particles and then reviewed the samples again "after a few months" and found particles; the investigation does not provide dates of events. In addition, the documentation does not specify how the investigation extended to other batches.
- C. A complaint of wrong label concentration identified for Combo Drops Lot (b) (4) was received on 03/02/21. Corrective actions involved relabeling of the vials and updating the label tracking form to include the review ingredient strength. However, a root cause was not

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investigated or determined. The investigation did not extend to other batches.

OBSERVATION 2

The accuracy, specificity and reproducibility of test methods have not been established.

Specifically, your method validation of ascorbic acid 500 mg/mL assay is inadequate because the validation parameters tested are not performed on the actual method used for release testing. You performed method validation studies on an HPLC method and use (b) (4) method for routine analysis. Comparison studies use (b) (4) to measure precision against HPLC results.

OBSERVATION 3

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

Environmental monitoring of personnel is not always performed after aseptic processing. Specifically, microbiological fingertip samples are not collected after the processing of small batches (of approximately less than (b) (4) units). For example, the following products were compounded and no fingertip or sleeve samples were collected:

- A. IC/B12/B2/B3/Canitine/Chromium/Lucine, Lot (b) (4), on 06/08/21
- B. Buprenorphine HCl, Lot (b) (4), on 05/07/21

OBSERVATION 4

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

Specifically, product release testing records from January 2020 to present were reviewed and do not include documentation of all data obtained during the analysis to include, but not limited to:

- A. System suitability determinations

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- B. Standard and sample preparations
- C. Calculations performed

This is a repeat observation from FDA-483, dated 06/24/19.

OBSERVATION 5

You did not retain reserve samples for drug products for one year after the expiration dates of the drug products.

On 08/16/21, you were unable to provide the retain sample for Magnesium Chloride, Lot (b) (4), citing that it was reviewed as part an incident/investigation (dated 03/01/21) and it was misplaced. This product was manufactured on 02/26/21, with BUD 08/26/21. In addition, you did not implement the stated procedure according to your SOP entitled *Protocol for Retention Samples* which states that the retain sample is discarded after the BUD.

OBSERVATION 6

Your outsourcing facility did not submit a report to FDA upon initial registration as an outsourcing facility identifying the drugs compounded during the previous six month period.

Specifically, the following products were compounded and not identified on your reports dated December 31, 2020 and/or June 30, 2021. Examples include, but are not limited to:

- Vitamin D (b) (4) /ml injection
- Buprenorphine 0.4 mg/ml injectable
- Alpha lipoic acid 25 mg/ml injection
- Sildenafil 110 mg capsules
- Tadalafil 10 mg troches
- Dihydroepiandrosterone 58 mg and pregnenolone 250 mg capsules
- Dihydroepiandrosterone 12.5 mg and pregnenolone 100 mg capsules

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- Dihydroepiandrosterone 25 mg and pregnenolone 100 mg capsules
- Minoxidil 5%, tretinoin 0.01%, triamcinolone 0.1% topical solution
- Minoxidil 5%, tretinoin 0.01%, finasteride 2.5% topical solution
- Naltrexone 2 mg capsules
- Dimercapto Succinate acid 250 mg capsules
- Liothyronine 35 mcg capsules
- Liothyronine 10 mcg capsules
- Benzocaine 20%, lidocaine 8%, and tetracaine 8% topical gel
- Benzocaine 20%, lidocaine 8%, and tetracaine 4% topical gel
- Lidocaine 23% and tetracaine 7% topical gel
- Lidocaine 4%, epinephrine 0.05%, tetracaine 0.5% gel
- Lidocaine 1% preservative-free buffered with 8.4% sodium bicarbonate injectable
- Alprostadil 10 mcg/ml penile injectable
- Tri-Mix Alprostadil 20 mcg, papaverine 30 mg, and phentolamine 4 mg/ml
- Tri-Mix Alprostadil 30 mcg, papaverine 30 mg, and phentolamine 2 mg/ml
- Phosphatidyl choline 5% and deoxycholate 4.2% injectable
- Testosterone 0.15% topical cream
- Testosterone 8 mg/ml topical gel
- Prednisolone 1% ophthalmic drops
- Mebendazole 100 mg capsules
- CoQ10 20 mg/ml in oil injectable
- Liposupreme: (b) (4)
[REDACTED]
mg/ml injectable
- Myer's cocktail: preservative-free vitamin C (b) (4); magnesium (b) (4) calcium (b) (4) injectable
- 7-Keto DHEA injectable

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- Acetyl cysteine 200 mg/ml injectable
- Estriol 2 mg suppositories
- Estriol 2 mg and testosterone 10 mg per gram topical gel
- Semorelin acetate 1 mg/ml injection
- Amphotericin B 50 mg, chloramphenicol 500 mg, hydrocortisone 10 mg/g otic powder
- Acetyl D-glucosamine 100 mg/ml injectable
- Hydroxocobalamin 1,000 mcg/ml injection

OBSERVATION 7

Bulk drug substances used by the outsourcing facility to compound drug products are not manufactured by an establishment that is registered under section 510 as required by section 503B(a)(2)(C). Specifically, the following establishments that supplied bulk substances to the outsourcing facility do not appear to be registered with the FDA:

- A. CoQ10 supplied by (b) (4) (sourced from (b) (4))
- B. Choline chloride supplied by (b) (4) (sourced from (b) (4))
- C. Benzyl benzoate supplied by (b) (4) (sourced from (b) (4))
- D. Sodium hydroxide supplied by (b) (4) (sourced from (b) (4))
- E. Inositol supplied by (b) (4) (sourced from (b) (4))
- F. Cyanocobalamin supplied by (b) (4) is sourced from (b) (4). (b) (4) is indicated to be in an "inactivated" status with FDA. Also, the cyanocobalamin COA from (b) (4) states "not for drug use."

***DATES OF INSPECTION**

7/27/2021(Tue), 7/28/2021(Wed), 7/29/2021(Thu), 7/30/2021(Fri), 8/03/2021(Tue), 8/04/2021(Wed), 8/05/2021(Thu), 8/06/2021(Fri), 8/11/2021(Wed), 8/16/2021(Mon), 8/19/2021(Thu), 8/23/2021(Mon), 9/02/2021(Thu), 9/03/2021(Fri)

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Jennifer Lalama
Investigator
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Date Signed 09-03-2021
011325

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."