DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	7/16/2019-8/1/2019* FEI NUMBER 3012465222

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert A. Myers , PhD.RPh,President	
FIRM NAME RAM Pharma, Inc	STREET ADDRESS 1125 Hollipark Dr
CITY, STATE, ZIP CODE, COUNTRY Idaho Falls, ID 83401	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

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

Specifically,

A) On 07/18/2019 during the production of(b) (4) 2mg/0.05mL for Injection, the "Pharmacist in Charge" was observed taking a fingertip sample from a gloved hand that was still wet following disinfection with sterile (b) (4), , before production began.

B) During review of your "Finished Product Sterility Testing" records which includes both environmental and personnel monitoring data from 11/30/2017-05/13/2019, approximately (b) (4) samples taken from inside the ISO5 LAFH were positive for growth. For example:

1) 11/30/2017 touch plate was positive for growth.

2) 12/04/2017 settling plate was positive for growth.

3) 06/11/2018 touch plate was positive for growth.

4) 08/17/2018 settling plate was positive for growth.

5) 10/19/2018 (positive for growth, plate type not identified)

No action was taken per SOP 08-004 "Environmental Monitoring-Microbial" and no alert level is established to prevent the possible contamination of sterile drug products **(This is a repeat observation from a previous inspection).**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bryan L Mcguckin, Investigator	X Bryan L Mcguckin Investigator Signed By: Bryan L. Mcguckin -S Date Signed: 08-01-2019 14:30:07	DATE ISSUED 8/1/2019

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C) The system for routine environmental monitoring of your classified zones, such as surface sampling, is currently conducted on (b) (4) in the LAFH and following (b) (4) cleaning as described in SOP 05-001. However, prior to 02/02/2019 no records could be provided that demonstrates a specific sampling plan utilized for all ISO classified rooms beyond (b) (4) viable air sampling.

D) Non-viable air sampling is not conducted during production **(This is a repeat observation from a previous inspection)**.

E) The (b) (4) into room (b) (4)", an unclassified room utilized during the production of sterile drug products, does not undergo routine environmental monitoring.

F) Alarm systems to monitor for potential breaches in air quality are currently not employed.

OBSERVATION 2

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,

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A) SOP 11-006 (b) (4) Validation" was updated and implemented on 07/02/2019 to include a biological indicator. However, there is no documentation to establish load mapping studies have been conducted.

B) Your firm has not validated any depyrogenation process for sterile glassware used in the production of "High-Risk" sterile drug products.

C) Your firm is using preservatives for sterile products produced as "multi dose". However, there is no data to establish products using said preservatives have been tested to demonstrate efficacy. **(This is a repeat observation from a previous inspection).**

OBSERVATION 3

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

Specifically,

On 07/18/2019 during the production of(b) (4) 2mg/0.05mL for Injection, I observed the use of sterile wipes rendered non-sterile having been left open on top of the LAFH for an unknown period prior to production. These wipes were subsequently used to clean inside the ISO5 zone and to clean equipment introduced into the ISO5 zone throughout production.

OBSERVATION 4

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There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

All stability data for your sterile products was requested in support of extended "Beyond Use Dates" used at your firm. Provided were "Technical Reports" which your firm established to support the use of extended BUD's.

A) Data provided supports sterility testing; no potency testing was conducted.

B) Accelerated studies were either not conducted or data not provided that demonstrates there are no degradant products formed or potency altered under such conditions.

C) Not all products have data to support the use of extended BUD's.

OBSERVATION 5

Each batch of drug product purporting to be pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

All finished sterile drug products reviewed undergo sterility testing at (b) (4) prior to release. However, not all sterile drug products are tested to ensure they are pyrogen-free. For example:

1. Dexamethasone 400mcg/0.1 Injection, Lot #: 201804091 was not tested for endotoxin prior to distribution.

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2. Lidocaine 1%/Phenylephrine 1.5% Solution PF, Lot #: 201806111 was not tested for endotoxin prior to distribution.

(This is a repeat observation from a previous inspection).

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

Your firm does not conduct potency testing for any finished drug products prior to distribution. For example:

1) Ephedrine sulfate 5mg/mL Injection-5mL Syringe, Lot #: 201810191 & Lot #: 201903132 was distributed without potency data.

2) Methylcobalamin 5mg/mL Injection Solution MDV, Lot #: 201901312 was distributed without potency data.

3) Dexpanthenol 250mg/mL Injection Solution MDV, Lot #: 201902012 was distributed without potency data.

(This is a repeat observation from a previous inspection).

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OBSERVATION 7

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

You firm has not established alert levels or initiated investigations into repeated microbial incursions into the ISO5 classified zone. From 11/30/2017-05/13/2019 approximately 15 microbial incursions were reported in your ISO5 LAFH. No action was taken until 12/05/2018 with the initiation of CAPA Report #: 2018-001. Incursions into the ISO5 LAFH continued after completion of the investigation conducted for CAPA Report #: 2018-001, for example:

1) 03/01/2019 touch plate positive for growth.

2) 05/13/2019 touch plate positive for growth.

No follow up investigations have been conducted to determine the cause of continued microbial incursions into the ISO5 LAFH.

*DATES OF INSPECTION

7/16/2019(Tue), 7/17/2019(Wed), 7/18/2019(Thu), 7/19/2019(Fri), 7/22/2019(Mon), 7/23/2019(Tue), 8/01/2019(Thu)

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