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 Industry Information: www.fda.gov/oc/industry	08/05/2013 - 08/23/2013* FEI NUMBER 3009864179

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Scott K. Morton, Executive Vice President

FIRM NAME	STREET ADDRESS
Pharmagen Laboratories, Inc	30 Buxton Farms Road Suite 110
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Stamford, CT 06905	Sterile injectable drug manufacturer

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:

QUALITY SYSTEM

OBSERVATION 1

There is no quality control unit.

Specifically,

A. There is no quality control unit (QCU) separate from production. The Pharmacy Manager currently operates in production of sterile drug products and approves their release.

B. There is no written and approved procedure describing the roles and responsibilities of the Quality Control Unit (QCU).

C. No written procedures have been signed as reviewed and approved by qualified personnel.

D. The following lots were distributed without release signature or prior to release signature from the Pharmacy Manager:
   a. Acetylcysteine Lot 04302013@22 distributed 05/20/13-06/18/13. This lot was not signed off as released.
   b. Nalbuphine Lot 06252013@29 distributed 07/02/13-07/30/13. This lot was not signed off as released.
   c. Sodium Phosphates Lot 04182013@25 released 05/07/13, distributed 05/01-06/25/13
   d. Dextrose PF Lot 05062013@12 released 06/03/13, distributed 05/31/13

OBSERVATION 2

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.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maya M. Davis, Investigator Sharon K. Thoma, Investigator	08/23/2013

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Your firm failed to investigate (i.e., investigate, implement corrective actions to prevent recurrence, and perform a health hazard) for product discrepancies and failures, which include but not are limited to:

A. Your firm failed to investigate an estimated 22 lots with discrepant results for microbial testing. For "inconclusive" results, your firm does not have an investigation, rationale or justification to support that these results are not sterility failures.

a. 16/22 lots had inconclusive (b) (4) results and were also tested with (b) (4) and/or USP <71> as follows:
   i. 10 lots were retested using (b) (4) with passing results: 8 of these lots were distributed (e.g. Sodium Phosphate Lot 04182013@25) and 2 were not (e.g. Dextrose Lot 02142013@21)
   ii. 7 lots were also tested using USP <71> with passing results: 5 lot were distributed (e.g. Acetylcysteine Lot 04302013@22) and 2 were not (e.g. Acetylcysteine Lot 07302013@24)
   iii. 5 lots were retested using (b) (4) with inconclusive results: 4 of these lots (e.g. Aminocaproic Acid Lot 05182013@1) were distributed and 1 was not (e.g. Potassium Phosphate Lot 06192013@24)

b. 3/22 lots had inconclusive results using USP <71> sterility testing (b) (4). According to your contract testing laboratory, inconclusive results in USP <71> is equivalent to turbidity. These lots were also tested with (b) (4) (1 vial only) with passing results.
   i. Calcium Chloride Lot 05012013@24, which was distributed 05/09/13
   ii. Calcium Gluconate Lot 04302013@26, released 05/09/13, distributed 05/08-14/13
   iii. Calcium Chloride Lot 04302013@21, which was not distributed

c. 1/22 lots had a sterility failure via (b) (4) with 5 fluorescent events (E) and 1 confirmed microorganism (M) detected, Sodium Phosphate Lot 03182013@15. This microorganism was not identified to genus or species level.

B. Your firm failed to investigate lots with rejected units. In addition, your firm does not track, trend, or maintain a log of vials rejected with reason for rejection.

a. 11/(b) (4) units of Sodium Phosphate Lot 04182013@25 were rejected for small black fibers and remainder of lot was released for distribution on 05/07/13.
b. 49/(b) (4) units of Dextrose Lot 04192013@21 were rejected with no reason recorded. Remainder of lot was released for distribution 05/20/13. This lot was reprocessed and pooled with other lots due to particulates per Pharmacist (b) (6).
c. 7/(b) (4) units of Dextrose PF Lot 05062013@12 were rejected and lot was released for distribution on 06/03/13. Reason for rejected vials not recorded but per (b) (6) this product has a problem with particulates.
d. 26/(b) (4) units of Calcium Chloride Lot 05182013@2 were rejected with no reason recorded for reject and lot was released for distribution 05/28/13.
e. 3/(b) (4) units of Nalbuphine Lot 06252013@29 were rejected with no reason record for reject and lot was not signed off as released and distributed on 07/02/13.

C. Your firm failed to investigate or reject the following lots of Dextrose that were never distributed. Per Pharmacist (b) (6) this product is problematic for particulates:

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a. Dextrose Lot 05292013@2 found in your quarantine area on 08/05/13.
b. Dextrose Lot 07032013@20 with 27/67 units rejected.

D. Your firm failed to investigate a stability failure for Super Tri-Mix Lot 10112012@1 when the Extended Analysis 2, dated 01/04/2013 and Extended Analysis 3, dated 01/18/2013 failed potency for prostaglandin on stability at the 90-day BUD/Expiration Date at 87.0% and 85.5%, respectively. Specification limits are [redacted] (b) (4) label claim of 20 mcg/mL or [redacted] (b) (4) cg/mL. Potency measured by the outside contract laboratory was 17.4 mcg/mL on 01/04/13 and 17.2 mcg/mL on 01/18/13. Lot 10112012@1 was distributed, e.g. order 239553 shipped 11/07/12

E. Your firm failed to investigate 3 units of unlabeled product (reported as mannitol by Pharmacist [redacted] (b) (6) with crystallization found in your quarantine area on 08/05/13.

OBSERVATION 3

A written record of each complaint is not maintained in a file designated for drug product complaints at the facility where the drug product was manufactured, processed or packed.

Specifically, complaint documentation and investigations were deficient as follows:

A. Complaints were not recorded at your firm until March 2013. Since March 2013, there have been approximately 62 complaints in your log, which is not comprehensive of all complaints, e.g.:
   a. Adverse Event reported to your firm regarding Baclofen Lot 03152013@2 was not included in your firm's complaint log
   b. Per [redacted] (b) (6) a physician ([redacted] (b) (6)) called in the week of 07/29/13 to report precipitates in an intrathecal product and this was not in the complaint log

B. Complaint records for 62 complaints consist of a log only. Complaint records lack comprehensive information, e.g.:
   a. name/strength of product
   b. lot number
   c. name of complainant
   d. nature of complaint
   e. lack of complaint investigation and no justification for not investigating
   f. reply to complainant

C. Complaint procedure does not discuss reporting requirements of serious adverse events to FDA.

PRODUCTION SYSTEM

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Stamford, CT 06905	Sterile injectable drug manufacturer

OBSERVATION 4

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

Specifically,

A. There is no process validation for the following deviations in the production of Dextrose Lot 04192013@21 to assure that the product met all applicable quality standards. This lot was:
   a. A pooling of three lots whereby [(b) (4)] vials of Dextrose Lot 03202013@21 was added to Lot 04192013@27 and Lot 04192013@21
   b. [(b) (4)] of the pooled material via [(b) (4)] not labeled for parenteral use and no data to support the [(b) (4)] is appropriate for pharmaceutical use
   c. Capping the bottle of [(b) (4)] material in an unclassified area after [(b) (4)] prior to [(b) (4)]
   d. [(b) (4)] sterilization of the pooled lot in batches with no data to support hold times

B. The following deficiencies were noted in [(b) (4)] use:
   a. The [(b) (4)] gauge used for [(b) (4)] is not calibrated. This gauge is used to test [(b) (4)] used to sterilize injectable drugs made from nonsterile ingredients.
   b. No [(b) (4)] testing performed to date for [(b) (4)] used with the repeater pump to aseptically fill sterile injectables (e.g. Bi-Mix, Tri-Mix, and backordered items (Calcium Chloride, Sodium Phosphate, Nalbuphine)).
   c. No microbial retention studies have been performed
   d. No [(b) (4)] qualification has been completed to date to demonstrate no loss upon drug [(b) (4)] and no interaction with the [(b) (4)] itself for all product formulations (e.g., [(b) (4)] used for the repeater pump).

C. The following deficiencies were noted with media fills:
   a. No growth promotion has been conducted to date on [(b) (4)] prepared media to demonstrate that the media supports growth and that the media has the proper pH per the manufacturer's instructions.
   b. Media fills do not simulate all aseptic operations performed (i.e. production using the [(b) (4)] with the repeater pump) or the size of batches filled.
   c. Media fills are not performed on all container closure systems (e.g. syringes of Atropine. Smallest and largest vials were not tested in media fills).
   d. Media fills completed on 02/12/13 for Pharmacist [(b) (6)], 02/13/13 for Pharmacist [(b) (6)], and 04/29/13 for Pharmacist [(b) (6)] does not identify the quantity of units prepared and used, the incubator used, the number of days incubated (i.e. date placed in and date taken out of incubator), and the pH of prepared media. In addition, there is no documentation on the preparation of media used and how it was prepared for [(b) (6)] on 04/29/13.
   e. Media fill for Pharmacist [(b) (6)] on 02/12/13, Pharmacist [(b) (6)] on 02/13/13, and Technician [(b) (6)] on 06/27/13

used [redacted] (b) (4) per <797> instruction preparation and reads to incubate at [redacted] (b) (4) days at [redacted] (b) (4) deg C. Documentation lacks: incubator used, time in/out, number of days incubated, pH of prepared media. Media fills were not stored at 20-25 deg C, only at 30-35deg C.

f. Certificate of Analysis for [redacted] (b) (4) does not identify organisms to the ATCC number.

g. Documentation requirements for media fills were not conducted per SOP 9.110.

D. The following was observed with respect to aseptic personnel practices:

a. Donning of gown without gloves on 08/05/13

b. No sleeve covers on 08/05/13, 08/08/13

c. Leaning with forearms on horizontal work bench surface where aseptic operations take place on 08/05/13, 08/08/13

d. Placing beaker from ISO 7 cart onto ISO 5 workbench without sanitizing the beaker on 08/05/13

e. Torso over work bench surface where products are mixed on 08/08/13

f. Exit from ISO 7 clean room to ISO 8 anteroom to retrieve supplies (e.g. syringe filter) and no glove change prior to re-entry into ISO 7 on 08/16/13

E. The following deficiencies were noted with respect to depyrogenation:

a. Your [redacted] (b) (4) depyrogenation oven is not qualified for use and the digital thermometer and temperature probe placed inside the oven have not been calibrated.

b. Your firm lacks a procedure for vial depyrogenation. Pharmacist [redacted] (b) (6) reported that [redacted] (b) (4) is used to rinse vials prior to depyrogenation while Pharmacist [redacted] (b) (6) reported that [redacted] (b) (4) is used. Your firm lacks a procedure describing how vials are washed and your washing is not validated to assure removal of pyrogens.

F. The following deficiencies were noted with respect to [redacted] (b) (4):

a. Lack of validation of [redacted] (b) (4) sterilization processes, e.g. for Dextrose preservative free for injection

b. The [redacted] (b) (4) is not qualified and calibrated for use. No load patterns, no heat distribution/penetration studies have been completed.

c. You do not record the results of the biological indicator results after sterilization process in order to show lethality of bio indicator (BI).

d. Your firm does not have validation data to demonstrate that stoppers [redacted] (b) (4) multiple times are not negatively impacted. There is no traceability or assignment of lot numbers on [redacted] (b) (4) runs conducted on stoppers. In addition, there is no endotoxin testing conducted on stoppers.

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

A. Non-sterile garb is used in classified areas in the production of sterile drug products, e.g. gown (no sleeve covers,

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used), boots, hair cap, beard cover, face mask, goggles.

B. Gloves were not changed between weighing of different ingredients, observed on 08/05/13

C. Vents to goggles were removed and goggles were worn on the forehead, leaving visible brows and skin around the eyes exposed, during sterile operations observed on 08/05/13.

OBSERVATION 6

Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices.

Specifically,

A. No employees have received cGMP training in 21 CFR 210/211.

B. Staff performing the following duties do not possess the education, training, or experience in microbiology:
   a. surface, personnel, and environmental monitoring
   b. reading of settling and contact plates
   c. reading of vials used in media fills

C. There is no documentation to support that staff performing visual inspection of sterile injectable product, which comprises all pharmacists and technicians, have adequate training.

OBSERVATION 7

The master production and control records for each batch size of drug product are not prepared, dated, and signed by one person with a full handwritten signature and independently checked, dated, and signed by a second person.

Specifically,

There is no Quality Control Unit approved master batch record and the Logged Formula Worksheets lack the following information to prevent mixups:

A. For 18/24 batch records (logged formula worksheets) reviewed, actual weight of ingredient was not recorded.

B. There is no second verification of components added to each batch at the time of component weighing and addition to the batch.

C. Product yield is not calculated.

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D. Labeling is not reconciled.

FACILITIES & EQUIPMENT SYSTEM

OBSERVATION 8

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. No smoke studies have been conducted to in any classified areas to date, including the clean room, the horizontal flow hood, and the [redacted] (b) (4) isolator. There is no assurance that [redacted] (b) (4) isolator adapted for use as a vertical laminar flow hood (front barrier removed) maintains adequate air flow patterns.

B. ISO 5 areas (e.g. horizontal flow hood) have not been qualified under dynamic conditions.

C. Deficiencies noted in the environmental monitoring program include but are not limited to:
   a. The normal microbial flora of the facility has not been determined.
   b. Monitoring is performed [redacted] (b) (4) and production of sterile product is approximately [redacted] (b) (4).
   c. The clean room facility surface sampling log demonstrates on 07/01/13 that [redacted] (b) (4) was stored at 30-35 deg C and on 07/24/13 that [redacted] (b) (4) was stored at 20-25 deg C and [redacted] (b) (4) at 30-35 deg C. [redacted] (b) (4) and [redacted] (b) (4) were not stored under optimum temperatures per USP to promote growth.
   d. CFUs found post cleaning are not identified to genus or species
   e. No rationale or data to support selection of sampling areas, e.g. ISO 5,7.
   f. Specific locations are not indicated on diagram used for collection of EM samples.
   g. Sampling does not include high traffic areas, e.g. laptop computer keyboards [redacted] (b) (4) repeater pump, pressure gauge for [redacted] (b) (4) clean room mops.
   h. Samples are not given specific locations for monitoring, e.g. ISO 7 floor rather than samples from specific quadrants.
   i. Samples are not always taken prior to cleaning, e.g. samples dated 07/29/13 were identified by the Pharmacist in Charge as being taken after cleaning.
   j. Personnel fingertips are not monitored in ISO 5 areas after each fill.
   k. No investigation of surface sample failures in ISO 7 on 01/29/13, 02/26/13, 03/13/13, 05/15/13, 05/21/13, 05/31/13, 07/01/13.
   l. [redacted] (b) (4) cleaning logs lack documentation performed for all required areas in ante room from January-May 2013
   m. Use of [redacted] (b) (4) paddles instead of settle plates during media fills, e.g. for [redacted] (b) (6) on 02/12/13, [redacted] (b) (6) on 02/13/13.

D. Deficiencies noted in the cleaning and disinfection of all classified areas (e.g. ISO 5) include but are not limited to:
   a. Bottles of [redacted] (b) (4) are transfilled from bulk bottles of [redacted] (b) (4) and there is no data for number of transfills that can be performed and not lot number traceability.
   b. Either [redacted] (b) (4) or [redacted] (b) (4) are used in cleaning and it is not recorded which is used in January 2013

E. [redacted] (b) (4) pressure differentials in classified areas have not been recorded from March 2013-Present.

F. There is no data to assure that the incubator in the clean room does not increase air particulate counts where sterile drug is produced. This incubator is used to store plates used in [redacted] (b) (4) testing for microorganisms.

G. There is no rationale or data to support location of the sink in an unclassified area where personnel about to perform aseptic operations wash their hands prior to entering the classified area.

OBSERVATION 9

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

Specifically,

Instrumentation for the following thermometers are not checked and calibrated to an NIST-traceable standard:
a. Incubators used for storage of environmental monitoring and media fills
b. Autoclave
c. Depyrogenation oven
d. Hot/stir plate in clean room adapted isolator used to mix all formulations
e. Freezer used for storage of products such as Bi-Mix and Tri-Mix
f. Dry heat blocks used for biological indicator tests for autoclave

OBSERVATION 10

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

A.) The following was observed in the ISO 5 clean room areas on 08/06/13:
   a. Yellow and white dried residue on/inside the grill and white streaks on the grill on the horizontal laminar flow used during production of sterile injectable product
   b. Yellow splatter marks on the grill on HEPA filters in the adapted isolator used for mixing of covered sterile injectable products.

These grills are not cleaned per Pharmacist [redacted] (b) (6) and there is no data to assure that lack of grill cleaning and these spots on the

grill do not have product impact.

B.) Contract third party who certifies your clean room states in Report [redacted] (b) (4) dated 06/19/13 for horizontal flow hood where aseptic operations taken place states that that "hood needs a good cleaning". There is no evidence that this document was reviewed or additional corrective actions were taken.

C.) The following was observed in the ISO 7 where the [redacted] (b) (4) ISO 5 workbenches for production are housed:

a. The prefilter from the ISO 7 clean room to the ante room was found visibly dirty on 08/06/13. Contract third party s wrote in report [redacted] (b) (4) dated 06/19/13 that "clean room prefilters need to be changed". Your firm has no records to demonstrate the regular maintenance is performed on HEPA prefilters in ISO 5,7,8 areas.
b. Apparent brown splatter marks on the ceiling of the clean room

LABORATORY CONTROL SYSTEM

OBSERVATION 11

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

Specifically,

[redacted] (b) (4) testing used by your firm for the release of product. There is no data to support that this method has been validated for products at your firm.
The [redacted] (b) (4) test method is used in lieu of USP <71> sterility testing and you do not have data to demonstrate that it is equivalent to or better than the USP method.

OBSERVATION 12

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

Specifically,

Your firm does not determine potency for all sterile injectable products. From August 2012-August 2013, no potency testing was performed for the following products:

a. [redacted] (b) (4) (75%) lots of Aminophylline, e.g. Lot 04052013@1 released for distribution 04/09/13
b. [redacted] (b) (4) (75%) lots of Acetylcysteine, e.g. Lot 04302013@22, not released and distributed 05/20/13-06/18/13
c. [redacted] (b) (4) (80%) lots of Aminocaproic acid , e.g. Lot 05182013@1

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d. (b)(4) (91%) lots of Calcium Chloride, e.g. Lot 05182013@2 released 06/03/13, distributed 05/31/13
f. (b)(4) (62%) lots of Nalbuphine, e.g. Lot 06252013@29 not released and distributed 07/02/13-07/30/13
g. (b)(4) (50%) lots of Dextrose PF, e.g. Lot 05062013@12 released 06/03/13 and distributed 05/31/13

OBSERVATION 13

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

Specifically,

A. There are no written stability program or product-specific protocols for the establishment of expiration/BUD dating, e.g. for all backordered drug products, Tri-Mix, Bi-Mix, Super Tri-Mix.

B. Products that have not been placed on a stability program which lack supportive data for the 90 day BUD/expiration dates include but are not limited to Sodium Phosphate 3mmol 10/15mL and Bi-Mix.

C. There is no stability data to support expiration dates of 180 days for frozen Tri-Mix, Super Tri-Mix, and Bi-Mix formulations.

D. Stability studies performed on your products are deficient as follows:
   a. Only one lot was put on stability for Tri-Mix, Super Tri-Mix (with failure at 90 days), Potassium phosphate, Nalbuphine, Dextrose, and Calcium Chloride
   b. Sterility and bacterial endotoxin testing are not testing at expiration
   c. No accelerated studies have been completed to date.

E. SOP 9.050 "BEYOND-USE DATING (BUD) OF COMPOUNDED PREPARATIONS" dated 10/22/12 lacks:
   a. Sample size
   b. Testing intervals
   c. Identification of potency/chemical test methods
   d. Preservative effectiveness studies

*** DATES OF INSPECTION:**
08/05/2013(Mon), 08/06/2013(Tue), 08/07/2013(Wed), 08/08/2013(Thu), 08/09/2013(Fri), 08/14/2013(Wed), 08/16/2013(Fri), 08/19/2013(Mon), 08/23/2013(Fri)

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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 judgement, 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."