DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	03/04/2013 - 03/21/2013* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Marco (nmi) Loleit, CEO

FIRM NAME	STREET ADDRESS
Lowlite Investments, Inc. D/B/A Olympia Pharmacy	6700 Conroy Windermere Rd Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32835-3500	Producer of sterile drug products

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

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

Specifically,

A. Oil based drug products which are prepared from non-sterile ingredients are not processed through a (b) (4) (b) (4). These products, such as Progesterone 100mg/ml Injectable and Estradiol Cypionate 10mg/ml Injectable are (b) (4) with a (b) (4) (b) The (b) is (b) (4) . The impact of the (b) (4) on the integrity of the (b) has not been evaluated.

B. There is a failure to validate the (b) (4) (b) used to sterilize injectable and ophthalmic drug products produced from non-sterile components, such as Mitomycin, Alprostadil, Papaverine, and Phentolamine. In addition, no (b) (4) bioburden limits have been established in order to determine if it exceeds the maximum retention capability of the (b)

C. (b) (4) sterilization process parameters for sterilization of drug products have not been validated and there are no established load patterns, for example:

1. Acetyl-D-Glucosamine with Chondroitin is filled into vials and (b) (4) at (b) (4) for at least (b) (4).
2. Methylprednisolone Acetate 80 mg/ml Injectable is filled into a serum vial and (b) (4) at (b) (4) (b) for (b) (4).
3. Bulk Metabolase Forte is (b) (4) in a (b) (4) beaker and then filled aseptically. Furthermore, the formula worksheet for batch number B0101 lacks any (b) (4) parameters.

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D. The (b) (4) used for sterilization of drug products, containers, and closures is supplied with (b) (4) which is not tested for endotoxin or sterility.

OBSERVATION 2

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

Specifically,

A. The (b) (4) which was performed for the first time on 3/1/13 does not simulate all aseptic operations conducted during normal filling of sterile products in the ISO 5 hood. The (b) only simulates (b) (4). This simulated process is not similar to routine filling processes, such as activities observed on 3/4/13 in which pre-mixed bulk sterile solution was transferred with a syringe from a bulk bag into open vials which were then hand stoppered after all of the vials were filled. There is no media fill simulation of lyophilizer loading and syringe filling.

B. Aseptic techniques observed on 3/4/13 were inadequate as follows:

1. The technician was observed picking up the stoppers with her gloved hand and placing them onto the filled vials. At this time, the operator's glove was observed to be torn. In addition, exposed skin was observed at the wrist due to the glove not being pulled up over the sleeve.

2. There was infrequent sanitizing of gloves, especially prior to re-entry into the ISO 5 hood after retrieving items from the ISO 6 buffer room.

3. The technician was observed passing her hands and arms over the top of open vials in the hood that were in the process of being filled.

C. On 3/20/13, technicians were observed to exit the clean room while still wearing their gowns. They retrieved materials off of the shelves and then re-entered the clean room without regowning.

D. Bags of stoppers and vials which have been (b) (4) are not wiped down with sterile disinfectant prior to being transferred into the buffer room and the ISO 5 hood.

E. There is no data to support continued sterility of previously opened bags of stoppers stored in the buffer room without being fully re-sealed.

F. Partially stoppered vials containing drug product to be lyophilized are transferred from the hood to the lyophilizer however the pathway is not entirely covered by HEPA filters.

OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, non-sterile Mitomycin API (a cytotoxic) in powder form has been used to prepare Mitomycin Ophthalmic products in the same ISO 5 hood where other non-potent drugs are prepared.

OBSERVATION 4

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

Specifically,

A. No active microbial air monitoring is performed in the ISO 5 hood each day during preparation of injectable drug products. The most recent passive monitoring was performed on 3/1/13; prior to that it was performed 10/26/12.

B. Microbiological monitoring of the employee's fingertips is not performed each day that a batch of sterile product is mixed and/or filled. The most recent operator monitoring was performed on 3/1/13; prior to that it was performed 10/26/12.

C. Microbiological monitoring of the ISO 5 hood surfaces is not performed at the end of each day that a batch of sterile product is mixed and/or filled. The most recent microbial monitoring was performed 3/1/13; prior to that it was performed 10/26/12.

D. The current monitoring program does not include any non-viable particle monitoring during formulation and filling of injectable products.

E. The (b) (4) used for air, surface and fingertip monitoring are incubated under ambient conditions on a shelf in the buffer room for (b) days rather than in a 30-35°C incubator for 48 – 72 hours as specified by the directions for use.

F. No microbiological monitoring of the air or surfaces is performed in the buffer room which surrounds the ISO 5 laminar air flow hood. The technicians stand in the buffer room while they are preparing injectable products in the hood and frequently retrieve items from the buffer area for use in the hood.

OBSERVATION 5

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

Specifically,

A. No static and dynamic airflow pattern studies (smoke studies) have been performed in the hood or 6 buffer room where injectable drug products are prepared.

B. There is no continuous monitoring of air pressure differentials from the classified buffer and ante rooms to the surrounding non-classified laboratory area.

OBSERVATION 6

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

Specifically, the gown, booties, hairnet, and facemask worn in the clean room are not sterile. The knee length gown only ties at the neck and waist and does not fully cover street clothes. In addition gowning does not provide complete coverage of the skin on the face and neck.

OBSERVATION 7

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

Specifically,

A. The suitability and efficacy of disinfecting agents and procedures have not been assessed to ensure potential contaminants are adequately removed from the surfaces in the classified areas. Routine cleaning procedures for the ISO 5 hood do not include the use of a qualified sporicidal cleaning agent at an established frequency.

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B. (b) (4) solutions are used to clean the surfaces of the ISO 5 laminar flow hood where injectable drug products are mixed and filled.

OBSERVATION 8

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, bulk drug products such as Ciprofloxacin 17 mg/ml Injection and CACO/COPPER 6.2 mg/ml INJECTION which are stored for future use may be re-opened or re-entered with a syringe in the ISO 5 hood (b) (4) Products are not consistently labeled with the initial date of opening or entry so as to prevent use after (b) (4). Furthermore, there is no data to support continued sterility of bulk drug products due to these practices.

OBSERVATION 9

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

There is no stability data to support expiration dates applied to injectable drug products and dates are extended beyond those specified in the firm's formula worksheets, for example:

A. Glutathione 200mg/ml Injectable lot K5428 was prepared on 11/28/12 and assigned an expiration date of 11/13 (1 year) although the formula worksheet specifies a (b) day expiry.

B. Vitamin B Buildup Plus Injectable lot K0014 was prepared on 11/14/12 and assigned an expiration date of 09/13 (10 months) although the formula worksheet specifies a (b) day expiry.

C. Methylprednisolone Acetate 80 mg/ml Injectable lot K4116 was prepared on 11/16/12 and assigned an expiration date of 11/13 (1 year) although the formula worksheet specifies a (b) day expiry.

D. Beta Alanine 100mg/ml & L-Carnosine 100mg/ml Injection lot K4419 was prepared on 11/19/12 and assigned an expiration date of 12/13 (13 months) although the formula worksheet specifies a (b) day expiry.

E. Naproxen 100 mg/ml Injectable lot K4115 was prepared on 11/15/12 and assigned an expiration date of 11/13 (1 year) although the formula worksheet specifies a (b) day expiry.

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OBSERVATION 10

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, there is no data to demonstrate that the firm's practice of (b) (4) glass vials and rubber stoppers used in aseptic filling operations renders them clean, sterile, and pyrogen free. Load patterns have not been established, and the cycles have not been validated. A color indicator on the exterior of the (b) (4) is used to assure sterility of the items processed.

OBSERVATION 11

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

Specifically endotoxin testing has never been performed on finished injectable drug products.

OBSERVATION 12

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, there is no justification for the sample size of (b) (4) for sterility testing.

*** DATES OF INSPECTION:**
03/04/2013(Mon), 03/05/2013(Tue), 03/20/2013(Wed), 03/21/2013(Thu)

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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."

Issued w/ 483 CMM 3/21/13