DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	11/12/2013 - 11/22/2013* FEI NUMBER 3004490277

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William B. Cheek, R.Ph, Pharmacy Manager/Co-Owner

FIRM NAME	STREET ADDRESS
Nature's Pharmacy & Compounding Center	752 Biltmore Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Asheville, NC 28803-2558	Producer of Sterile Drugs

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

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

Specifically,

Your firm has produced and distributed over [redacted] (b) (4) medication orders of sterile drugs in the past year, for which the following has not been performed on any drug product processed and distributed by your firm:

A. Assay or product identification testing for any sterile injectable or sterile opthalmic drug product.

B. Sterility Testing for any drug product has not been performed.

C. Endotoxin Testing for any drug product has not been performed.

OBSERVATION 2

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

Specifically,

A. The processing of sterile products via [redacted] (b) (4) methods has not been validated. No media fills/process simulations have eyer been performed.

B. There is a failure to validate the [redacted] (b) (4) used to sterilize injectable and ophthalmic drug

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products such as: Lidocaine 4% Solution/Personal Lubricant 1:1 Gel, Tri-Mix (Erectile Dysfunction Injection),Dexamethasone Ophthalmic Solution PF, and 5-Fluorouracil Ophthalmic Solution. These products are produced from nonsterile components.

C. Pre-and post [redacted (b) (4)] of sterilizing [redacted (b) (4)] used in [redacted (b) (4)] processes have never been conducted to ensure that these [redacted (b) (4)] meet specification, are properly installed and intact during [redacted (b) (4)]

OBSERVATION 3

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

Specifically,

A. Active or passive microbial air monitoring has never been performed in the [redacted (b) (4)] during preparation of injectable or ophthalmic drug products.

B. Microbiological monitoring of operators performing aseptic preparations has not been conducted.

C. Microbiological monitoring of the surfaces within the [redacted (b) (4)] have not been conducted during or at the end of sterile filling of a batch.

D. Annual certification of the [redacted (b) (4)] does not include testing for viable and non-viable particulates.

E. There is no established environmental monitoring program.

OBSERVATION 4

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

Specifically,

A. Smoke studies have not been performed within the [redacted (b) (4)] to verify that operators and processing equipment do not alter or impede the unidirectional cascade of air from the HEPA filters within the ISO

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3 classified [redacted] (b) (4) where injectable and ophthalmic drug products are processed.

B. There is no continuous monitoring of air pressure during preparation of injectable or ophthalmic drug products within the [redacted] (b) (4)

OBSERVATION 5

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

Specifically,

A. The suitability and efficacy of the cleaning and disinfecting agent used has not been assessed to ensure potential contaminates are adequately removed from the surfaces of the [redacted] (b) (4) and other areas where sterile drug products are processed.

B. [redacted] (b) (4) and lint-free, nonsterile wipes are used to clean the surfaces of the [redacted] (b) (4), hood, and countertops where injectable and ophthalmic drug products are mixed and filled.

C. The [redacted] (b) (4), classified as ISO 3 and used to aseptically process sterile products is located in an unclassified area.

OBSERVATION 6

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

Your firm does not use sporicidal cleaning agents within the [redacted] (b) (4), on counter top or other product contact surfaces, or to clean the [redacted] (b) (4) Mixer used to process sterile products.

OBSERVATION 7

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

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Hair covers are not worn, and the laboratory coats and gloves that are worn during the aseptic processing of drug products are not sterile. The sterile product is potentially exposed to increased bioburden from skin and hair particles not contained by these garments.

OBSERVATION 8

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

Specifically,

Your firm produces injectable drug products, sterile ophthalmic solutions and other drug products. The "Days to Exp" identified on formula worksheets and used to calculate expiration dates of finished products are not supported by stability studies. There is no assurance, with the lack of appropriate scientific data, that your sterile drug products will remain sterile or maintain potency throughout the expiry period. You solely rely on scientific literature or vendor supplied information to establish such dates seen, for example, on the following formulation worksheets:

Lidocaine 4% Solution/Personal Lubricant Gel - (each component: Preserved Water - Days to exp. 30; Hydroxyethylcellulose 3% gel, Days to exp. 720, Lidocaine 4% solution, Days to exp. 180), the finished product is labeled with a year expiration date.
Tri-Mix Injections(Prost E1 20/Papav30/Phent 1/ml) - Days to exp. 180
Vitamin B12 Injections (Methylcobalamin 5000mcg/ml) - Days to exp. 180
Cyanocobalamin (B12) Preservative -free 1000mcg/ml Injectable - Days to exp. 90
Dexamethasone(Preservative-Free) 0.05% Opthalmic Solution - Days to exp. 14
Dexamethasone 01.%/Tobramycin 0.3% Opthalmic Solution PF- Days to exp. 30
5-Fluorouracil (P-F) 1% Opthalmic Solution - Days to exp. 7
Folic Acid (Preservative Free) 10mg/cc Injectable - Days to exp. 60
Methotrexate Intraocular 400mcg/0.1cc injectable - Days to exp. 3
Vitamin A (olive oil) 0.01% Opthalmic - Days to exp. 180

OBSERVATION 9

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

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Your firm has not established and approved written procedures for any of the operations conducted, including sterile drug processing, testing procedures, stability program, quality assurance, etc.

*** DATES OF INSPECTION:**
11/12/2013(Tue), 11/13/2013(Wed), 11/15/2013(Fri), 11/19/2013(Tue), 11/22/2013(Fri)

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