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	4/17/2017-4/21/2017
	FEI NUMBER 3011158388

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou W. Kennedy , President and Owner

FIRM NAME	STREET ADDRESS
Nephron Pharmaceuticals Corporation	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	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 WE OBSERVED:

Laboratory Control System

OBSERVATION 1

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

Your firm has not performed aseptic process simulations to validate the Phenylephrine Hydrochloride aseptic sterilization process to provide evidence and assurance that sterility is maintained throughout (b) (4) activities of the process.

OBSERVATION 2

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

Specifically,

A. Your current procedure, SOP.QC.4301, "Visual Inspection of Compounded Sterile Preparations, version 1.0", in addition to (b) (4) tasked with performing the 100% visual inspection of finished product to detect container defects and product contaminates, do not include a representative library of potential defects to ensure that your operators are effectively trained and qualified to carry out these tasks. Additionally, (b) (4) s are based on the

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	Rachael L Cook, Investigator (CTNH) Bonita S Chester, Investigator Diane P Goyette, Regulatory Counsel	4/21/2017 X Rachael L Cook Rachael L Cook Investigator (CTNH) Signed by: Rachael L Cook -5	4/21/2017

ability of the operator to detect particles and defects (b) (4) whereas currently you (b) (4) (b) (4)

B. Your firm has not defined defect categories typically found during visual inspections of finished product nor do you perform trending of such defects for continual process quality improvements.

Quality System

OBSERVATION 3
The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, SOP.CP.1501, Supplier Vendor Quality Program, is not fully followed in that you have not established (b) (4) as required by your SOP, with (b) (4) (b) (4) reviewed.

Packaging and Labeling System

OBSERVATION 4
The container labels of your outsourcing facility's drug products are deficient.

Specifically, the following products did not have your firm address and/or phone number listed on the syringe label:

A. PF-Glycopyrrolate 1mg/5ml label lacks firm address and phone number.

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B. PF-Neostigmine 2mg/ml, 3mg/3ml, 4mg/4ml, and 5mg/5ml lack firm address and phone number.

C. PF-Atropine 1.2mg/3ml label lacks firm address and phone number.

D. Phenylephrine 0.4mg/10ml, 0.8mg/10ml, and 1.0mg/10ml labels lack firm phone number.

E. Succinylcholine 200mg/10ml label lacks firm phone number.

4/21/2017 4/21/2017

X Bonita S Chester
Bonita S Chester
Investigator
Signed by: Bonita S. Chester -S

X Diane P Goyette
Diane P Goyette
Regulatory Counsel
Signed by: Diane P. Goyette -S

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