

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Fax: (781) 596-7896	DATE(S) OF INSPECTION 07/21/2008 - 08/06/2008*
	FBI NUMBER 3005881167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Gregory A. Conigliaro, General Manager

FROM NAME Ameridose LLC	STREET ADDRESS 50 Fountain St
CITY, STATE, ZIP CODE, COUNTRY Framingham, MA 01702-6211	TYPE ESTABLISHMENT INSPECTED 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 | OBSERVED:

OBSERVATION 1

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, the firm manufactures stock solution of an additive made from an Active Pharmaceutical Ingredient received and performs a potency, sterility, and endotoxin testing on the additive, and then manufactures an Admixture for review and release by the Clean Room Pharmacist and Freight Room Pharmacist prior to shipment. There is no potency or identity test done on the finished drug product, and the product is shipped immediately and prior to the ^{(b) (4)} day sterility test results are received by the firm. Three examples are as follows: a) Fentanyl/Bupivacaine in 0.9% NaCl Lot#07152008@134 manufactured on 7/16/08 and shipped immediately; b) Sufentanil/Ropivacaine 0.4 mcg/0.2% ml Cassette Lot#07082008@136 manufactured on 7/09/08 and shipped immediately; and c) Oxytocin added to LR 20 units/ 1000 ml INJ BAG Lot#07142008@3 manufactured on 7/14/08 and shipped on 7/16/08. The firm SOP 9.060 Sterility Product Process VER 1 dated 7/17/06 under 9.0 PROCEDURE reveals the statement at 9.1.5 "Due to limited Beyond Use dating on our products, products free of contamination...shall be released on day ^{(b) (4)} by the quarantine Pharmacist".

OBSERVATION 2

Written procedures are lacking which describe in sufficient detail the identification, sampling, testing, approval, and rejection of components.

Specifically, SOP 5.010 Product Procurement, Receipt and Inspection Version 1.0 dated 7/17/06 does not address how the received active pharmaceutical ingredients are sampled, tested and identified by a test method shown in the USP or verified and validated to be equivalent to a known method in the USP. The firm receives a Certificate of Analysis on the Active Pharmaceuticals received and has validated the test results on the Certificate of Analysis of the initial lots from the suppliers, along with periodic tests on future lots received; however, some but not all API lots received have a specific identity test done on them. For example, the active pharmaceuticals for Hydromorphone HCL Lot#65723/C and 65300/E, and Ropivacaine 64719 were received by the firm and not specifically identity tested by test methods shown in the USP.

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STREET ADDRESS

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Framingham, MA 01702-6211

TYPE ESTABLISHMENT INSPECTED

Drug Manufacturer

OBSERVATION 3

The master production and control records are deficient in that they do not include a statement of theoretical yield and minimum, maximum, and yield percentages.

Specifically, a review of two Master Production records (Master Formula Worksheets) revealed no statement of theoretical yield nor a percentage range of theoretical yield that the produced batch should fall within. This can be seen in the following two Master production (Formula Worksheet) examples: a) Fentanyl (as citrate) in SWFI 50 mcg/ml 4000 ml Stock Solution, and b) Oxytocin in SWFI 10 units/ ml 4000ml Stock Solution.

OBSERVATION 4

Batch production and control records do not include results of the inspection of the packaging and labeling area before and after use for each batch of drug product produced.

Specifically, a review of Batch Formula Worksheets for both stock solution and finished product revealed that the firm does not document the line clearance inspection of the packaging and labeling area before and after use. For example, a) Oxytocin in SWFI 10 units/ml 4000 ml Stock Solution Lot#06172008@130 made 6/18/2008, and b) Oxytocin added to LR 20 units/1000 ml INJ BAG Lot#07162008@13 made 7/16/08 do not include instructions or have documented a line clearance before and after the packaging and labeling of the products involved.

OBSERVATION 5

The batch production and control records are deficient in that they do not include a statement of the actual yield and percentage of theoretical yield.

Specifically, a review of Batch Formula Worksheets for both stock solution and finished product revealed that the firm does not have a statement of the actual yield and the percentage of theoretical yield at the completion of the process. For example, there is no actual yield or percentage of theoretical yield noted in the following two Formula Worksheets: a) Oxytocin in SWFI 10 units/ml 4000 ml Stock Solution Lot#06172008@130 made 6/18/2008 (b) (4), and b) Oxytocin added to 0.9% NACL 30 units/ 500 ml INJ BAG Lot#07162008@27 for 432 bags made 7/16/2008 (b) (4).

OBSERVATION 6

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically, during the review of several SOPs it was noted that the firm was not following what was expected as noted in the following two documents:

- a) SOP 9.100 Sterile Technique Qualification (Media Fills) VER 2 dated 6/16/08 under 10.12 response to Positive results refers to "retraining" only throughout the section, and does not refer to the firm's Out of Specification Procedure SOP 3.030 for positive test result follow-up; and b) SOP 6.021 Quality Assurance Sample Process and Library VER 1 dated 6/11/07

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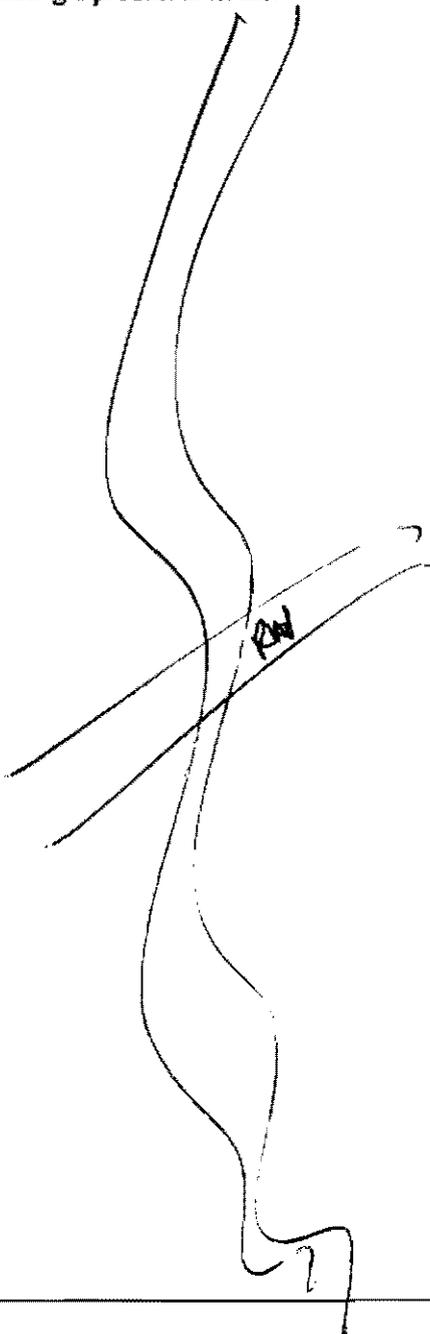
STREET ADDRESS

50 Fountain St

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reveals under 9.4 Testing of Q A Sample a section on "lot samples for in house Lab testing" when there is currently no in house lab testing or capabilities of testing a product in house.



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*** DATES OF INSPECTION:**

07/21/2008(Mon), 07/22/2008(Tue), 07/23/2008(Wed), 07/28/2008(Mon), 07/29/2008(Tue), 07/30/2008(Wed), 08/04/2008(Mon), 08/05/2008(Tue), 08/06/2008(Wed)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Richard H. Penta
8/6/08

Richard H. Penta, Investigator

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