DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	04/28/2009 - 05/04/2009* FEI NUMBER 3007026789

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Omar R. Bonada, Owner/President

FIRM NAME	STREET ADDRESS
Clarcon Biological Chemistry Laboratory Inc.	1815 W 4000 S Bldg 4
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Roy, UT 84067-3102	OTC 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 I OBSERVED:

OBSERVATION 1

There is no quality control unit.

Specifically, Dr. Bonada stated that he claims sole responsibility for functions performed by the quality control unit and is also responsible for the manufacture of finished product. The QCU and its responsibilities are not in writing.

OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the following validations have not been established or performed:
(1) drug manufacturing process validation,
(2) manufacturing equipment cleaning validation,
(3) "Purified Water" manufacturing process validation
(3) laboratory methods validation

OBSERVATION 3

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.

Specifically, the firm does not have any written master production and control records or written procedures describing their preparation.

OBSERVATION 4

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, (b) (4) batch records for lots manufactured between 4/2006 to 4/30/09 were reviewed and were missing the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R. Dionne, Investigator	05/04/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	04/28/2009 - 05/04/2009* FEI NUMBER 3007026789

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Omar R. Bonada, Owner/President

FIRM NAME	STREET ADDRESS
Clarcon Biological Chemistry Laboratory Inc.	1815 W 4000 S Bldg 4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Roy, UT 84067-3102	OTC Drug Manufacturer

following:

(1) specific identification of each component and in-process material;
(2) in process and laboratory control results;
(3) inspection of the packaging and labeling area before and after use;
(4) statements of actual and theoretical yields;
(5) any labeling control records including a sample of labeling used;
(6) description of drug product containers;
(7) any sampling performed;
(8) identification of person performing the manufacturing processes;
(9) any investigation made according to 21 CFR 211.192; and
(10) results of examinations made in accordance with 21 CFR 211.134.

OBSERVATION 5

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 does not test finished product to determine the identity and strength of the active ingredient, benzalkonium chloride.

OBSERVATION 6

Employees are not given training in current good manufacturing practices.

Specifically, the firm has no documentation to support that firm personnel have been trained in current good manufacturing practices for drug manufacturing.

OBSERVATION 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the firm does not have any written procedures.

OBSERVATION 8

All compounding and storage containers and major equipment used during the production of a batch of drug product is not properly identified at all times to indicate contents and the phase of processing of the batch.

Specifically, there were various unidentified containers located in the production and finished goods storage rooms which were not identified as to the contents, batch number, or phase of processing. These included as identified by Dr. Bonada:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R. Dionne, Investigator	05/04/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	04/28/2009 - 05/04/2009* FEI NUMBER 3007026789

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Omar R. Bonada, Owner/President

FIRM NAME	STREET ADDRESS
Clarcon Biological Chemistry Laboratory Inc.	1815 W 4000 S Bldg 4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Roy, UT 84067-3102	OTC Drug Manufacturer

(1) on the production floor there was one vertical white plastic container with approximately (b) (4) gallons & one horizontal white plastic container with approximately (b) (4) gallons of finished product.
(2) in the finished goods storage there were a total of (b) (4) plastic blue drums with approximately (b) (4) gallons each of finished product.

OBSERVATION 9

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

Specifically, the firm does not have a written or established stability testing program. Additionally, the firm could not supply stability data to support any expiration dating for their finished products located in the finished product storage areas of the facility; some of which were identified as being manufactured in 2007.

OBSERVATION 10

A sample which is representative of each lot in each shipment of each active ingredient is not retained.

Specifically, samples are not retained for any lots of finished products or active ingredients.

OBSERVATION 11

Records are not kept for the maintenance, cleaning, sanitizing, and inspection of equipment.

Specifically, the firm does not maintain any records pertaining to the equipment used in the manufacturing process.

OBSERVATION 12

There is a lack of written procedures assigning responsibility, providing cleaning schedules, and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically, the firm does not have any written procedures for the maintenance of the facility.

OBSERVATION 13

Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval, and rejection of components, drug product containers, and closures.

Specifically, the firm has no written procedures for related to components, drug product containers, and closures.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	04/28/2009 - 05/04/2009* FEI NUMBER 3007026789

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Omar R. Bonada, Owner/President

FIRM NAME	STREET ADDRESS
Clarcon Biological Chemistry Laboratory Inc.	1815 W 4000 S Bldg 4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Roy, UT 84067-3102	OTC Drug Manufacturer

OBSERVATION 14

Procedures designed to assure that correct labeling are used for drug products are not written.

Specifically, there are no written procedures for the receipt, review, approval, release, and use of drug product labeling and these activities are not being performed.

OBSERVATION 15

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically, the firm does not have an established process in place for the receipt, documentation, or investigation of complaints.

OBSERVATION 16

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary.

Specifically, the firm has no written distribution procedures in place. Although batch numbers are recorded on the batch records and invoices, the lot numbers of the components are not documented on any manufacturing or distribution records.

OBSERVATION 17

Procedures describing the warehousing of drug products are not established.

Specifically, the firm has no established procedure describing the warehousing of drug products.

OBSERVATION 18

Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product.

Specifically, the firm has not conducted any Annual Product Reviews for any of their manufactured products.

*** DATES OF INSPECTION:**
04/28/2009(Tue), 04/29/2009(Wed), 04/30/2009(Thu), 05/04/2009(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R. Dionne, Investigator	05/04/2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	04/28/2009 - 05/04/2009* FEI NUMBER 3007026789

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Omar R. Bonada, Owner/President

FIRM NAME	STREET ADDRESS
Clarcon Biological Chemistry Laboratory Inc.	1815 W 4000 S Bldg 4
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Roy, UT 84067-3102	OTC Drug Manufacturer

MRD 5/4/09

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R. Dionne, Investigator Matthew R. Dionne	05/04/2009