DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	09/03/2014 - 09/05/2014 FEI NUMBER 2511349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nalin C. Parikh, President

FIRM NAME	STREET ADDRESS
High Chemical Company, Div of National Generic Distributors	3901 Nebraska Ave Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Levittown, PA 19056	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 WE OBSERVED:

The following Observations pertain to production of Sarapin Injection (b) (4) Multiple Dose Vials:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, the investigation into the color change and appearance failure of 24 and 36 month stability samples for finished product lot (b) (4) has not been completed. The lack of an investigation was cited on the 9/7/12 Form FDA 483 (Observation 1) and discussed during the 12/12/12 Regulatory Meeting. Samples were not provided to a laboratory for analysis until 6/23/14. The investigation remains in-progress so no preventive action has been taken. SOP (b) (4) does not include timeframes for initiating and completing investigations.

OBSERVATION 2

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically, 3 out of 8 receipts of raw material Distilled Water in the past two years failed Total Organic Carbon (TOC) testing but were released and used in production. The specification is ((b) ppm. The out-of-specification TOC results for incoming Distilled Water were:

Receiving Number	TOC (ppm)
(b) (4)	(b)
(b) (4)	(b)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R Noonan, Investigator Derek S. Dealy, Investigator CRAIG D. ZALATA, INVESTIGATOR	09/05/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	09/03/2014 - 09/05/2014 FEI NUMBER 2511349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nalin C. Parikh, President

FIRM NAME	STREET ADDRESS
High Chemical Company, Div of National Generic Distributors	3901 Nebraska Ave Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Levittown, PA 19056	Drug Manufacturer

(b) (4) | (b)

SOP (b) (4)(b) (4)(b) (4)(b) (4), requires that raw materials meet specifications before use.

OBSERVATION 3

The establishment of specifications including any changes thereto, are not drafted by the appropriate organizational unit.

Specifically, the acceptance criteria for raw materials Dried Pitcher Plant and Distilled Water were not prepared or approved by the Quality Department.

Failure to establish quality-approved acceptance criteria for Dried Pitcher Plant or Distilled Water is a recurring deficiency from the 9/7/12 Form FDA 483 (Observation 5), 12/3/08 Form FDA 483 (Observation 1), 11/20/06 Form FDA 483 (Observation 4), and 12/1/05 Form FDA 483 (Observation 2).

OBSERVATION 4

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

Specifically:

a) SOP (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4), does not indicate a specification for 25 µm particulate matter in finished product.

b) The Stability Protocol and SOP (b) (4)(b) (4)(b) (4)(b) (4)(b) (4), mistakenly indicate a lower limit for endotoxin of (b) (4)(b) (4) in finished product. The documents were approved by quality personnel on 3/10/14.

OBSERVATION 5

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, the reliability of supplier Certificates of Analysis for raw materials (e.g. Benzyl Alcohol NF) is not verified such as by third party analysis at appropriate intervals.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R Noonan, Investigator MRN Derek S. Dealy, Investigator DSD Craig D. Zalatta, Investigator CDZ	09/05/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	09/03/2014 - 09/05/2014 FEI NUMBER 2511349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nalin C. Parikh, President

FIRM NAME	STREET ADDRESS
High Chemical Company, Div of National Generic Distributors	3901 Nebraska Ave Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Levittown, PA 19056	Drug Manufacturer

OBSERVATION 6

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

Specifically, an equipment cleaning and use log is not maintained for the vacuum filtration system used to filter the distillate.

OBSERVATION 7

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

Specifically, there is no written procedure describing the requirements for annual product reviews such as timeframes for completion. For example, the 2013 annual product review was not completed until 5/5/14.

OBSERVATION 8

Employees are not given training in written procedures required by current good manufacturing practice regulations.

Specifically, the Record of Training checklist does not ensure that employees complete annual refresher training on all applicable written procedures as required by SOP (b) (4)(b) (4)(b) (4)(b) (4). For example, the Manufacturing Supervisor's 2014 procedure training did not include all his responsibilities such as equipment calibration, housekeeping, and recordkeeping.

Inadequate employee training on applicable written procedures is a repeat observation from the 9/7/12 Form FDA 483 (Observation 9).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew R Noonan, Investigator Derek S. Dealy, Investigator Craig D. Zagata, Investigator	09/05/2014