DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	11/06/2012 - 11/09/2012
	FEI NUMBER 1221426

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark Woelfel, President/Cheif Operating Officer

FIRM NAME	STREET ADDRESS
Boston Analytical, Inc.	8 Industrial Way Unit D3
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Salem, NH 03079-2837	Control Testing Laboratory

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:

OBSERVATION 1

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

Specifically, the following SOPs were not followed:

a.) SOP P-1050, Version 16 Laboratory Investigation Policy, states all unexpected, out of trend or out of specification results are to be investigated however this was not followed for the following samples analyzed:

- Monosodium Glutamate Project #(b) , Sample # (b) (4) Assay tested on 07/12/13 reported an OOS result of 78.46. Analyst did not follow SOP P-1050 and conduct a Laboratory Investigation. The chemist re-assayed the sample by performing a step not described in test procedure and reported the retest results of 99.84%. The C of A issued to the customer reported.

- L-aspartic Monosodium Salt (Project # (b) , Sample #(b) (4) Identification Test reported an unexpected result of inconclusive color change. Analyst did not follow SOP P-1050 and conduct a Laboratory Investigation. The chemist increased the concentration using a procedure not described in test procedure, re-analyzed sample and reported the retest results of 99.84%. The C of A issued to the customer reported and did not indicate the results were reported from a retest as indicated in SOP.

b.) SOP P-1050, Version 16, Laboratory Investigation Policy, is not being followed which states testing into compliance without regards for scientific justification is not acceptable. For analysis of Levofloxacin (Project Number (b) , Sample #(b) (4)), Assay and Impurities test reported OOS results on 10/06/11, the sample was tested three times and the third analytical findings were reported on C of A.

c.) SOP P-510, Version Number: 12 Log-In of Samples for Testing describes procedure for logging in samples into computer system; however it does not include logging in of all samples as they are received the Sample Log-In Area. There is no traceability of samples received and stored in Sample Log-In Area. During inspection, samples were observed stored in the Sample Log-In Area with no sample submission forms and employee stated that all samples are not logging into computer upon receipt.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charisse K. Green, Investigator Abdur-Rafay Shareef, Investigator SAMUEL MATHEW, Chemist, Samuel Mathew	11/09/2012

d.) Firm not completing testing of stability of samples prior to the "Test by date" as stated in SOP P-645, Version 11, Initiating and Removing Stability Studies. Morphine Sulfate ER 60mg Tablets, Project #(b) (4) 4, Sample # (b) , Sample pull date 10/01/2012 and test on 11/01/2012.

e.) SOP P-1130, Version 11 Client Complaint Program states all client complaints are to be closed out within (b) (4) of the opening of the complaint. For CO-12-0029, date of contact for complaint is 02/10/12, complaint closed on 03/14/12.

OBSERVATION 2

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

a.) Specifically, described in SOP P-900 General Analytical Procedures not following test procedures for analysis of the following samples:

- Levofloxacin (Project Number (b) , Sample (b) (4)), Assay test and Impurities test not being followed according to USP 34.
- Sodium Bicarbonate (Project Number (b) Sample Number (b) (4)), the Identification test of Bicarbonate was not performed as stated in USP 34<191>.
- Sodium Bicarbonate (Project #(b) , Sample # (b) (4) Project #(b) (4) Sample (b) (4) 8) (Project # (b) 5, Sample # (b) (4) 3); the Limit of Arsenic test was not performed as stated in USP 34<211> Method I.

b.) SOP P-1913 How to Use Electronic Laboratory Notebooks, does not specify when data should be entered into electronic laboratory notebooks. During inspection it was observed while performing Assay of Tramadol HCl tablets 50 mg (Sample Number (b) (4) 26) using Procedure (b) (4) the analyst was recording the raw data for the standard weight on the volumetric flask.

c.) Inadequate Deviation Report prepared and followed for the following samples analyzed:

- Deviation Report, 11-0107 for Project Number (b) (4) Bleach Solution and Deviation 11-0109 Project Number (b) 4, Bleach Solutions and future Bleach Solution Samples tested post 6/2/11. Modification was made to the USP 34 Monograph for Sodium Hypochlorite Topical Solution. However, one reagent, Bleach was modified and subsequent reagents acetic acid and potassium iodide ratio were not correspondingly changed.

d.) Inadequate Technical Review and Quality Assurance review according to SOP P-1100 Version 10, Technical Review and Quality Assurance Release for the following records:

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- Project Number (b) Sample Number (b) (4) 6, Sodium bicarbonate
- For Samples (b) (4) Limit of Arsenic test USP 34<211> Method I
- Deviation Report 12-0221 and Deviation 12-0190
- Instrument Maintenance Form, Instrument (b) (4) date 30 Oct 2012, and Instrument (b) (4) 069

OBSERVATION 3

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically,

a.) Introduction to cGMPs training records for Director of Chemistry Laboratories not signed by trainer.

b.) According to training records analyst received training in HPLC Analysis dated 11/05/12, however while observing analyst conducting HPLC analysis the analyst also could not identify the precipitate that was present in the sample preparation.

c.) Two new analyst in-training stated they could independently analyze samples using Dissolution, HPLC, and UV-Visible Spectrophotometer equipment; however training records received on 11/7/12 did not indicate they were trained.