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	3/30/2026-4/1/2026
	FEI NUMBER 3014032983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Timothy G. Joy, Chairperson & COO

FIRM NAME	STREET ADDRESS
Neva Analytics, LLC	1851 Lefthand Cir Ste D
CITY, STATE, ZIP CODE, COUNTRY Longmont, CO 80501-6799	TYPE ESTABLISHMENT INSPECTED Contract 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 I OBSERVED:

OBSERVATION 1

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

Specifically,

1. SOP-1005, Handling Deviations and CAPAs, v2.0 states in section 7.4.1, "CAPAs may be generated in response to a deviation, OOS, Regulatory Inspection, internal audit, client audit, or at the discretion of QM" . Your firm submitted corrective actions to the Agency as responses to the four observations listed on the FDA Form 483 Inspectional Observations and two verbal observations issued during the previous inspection in February 2019. However, your firm failed to govern corrective actions under SOP-1005. Thus, adequate root causes and effectiveness of corrective actions could not be determined.

   CAPAs were either performed inadequately or not initiated for the following previous inspectional observations:

   Observation 1: A written record of the program along with appropriate validation data has not been maintained in situations where backup data is eliminated by computerization or other automated processes.

   a. The Software (b)(4) " used to execute stability analysis for HPLC assays for (b)(4) and (b)(4) and (b)(4)

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(b)(4) and (b)(4) was not validated. CAPA 006 was initiated on 13 May 2019, but it was inadequate.

b. The Environmental/Stability Chamber Model (b)(4), Equipment ID: 3046-1, Temperature (b)(4) was not validated and mapped. No CAPA/Deviation was initiated.

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. Your firm did not have a formal established procedure for investigating Out of Specification [OOS] results. No CAPA/Deviation was initiated.

Observation 3: Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically,

b. Analysts were capable of deleting executed sequences and results from the (b)(4) where the software path saves the executed analyses for HPLC. CAPA 006 was initiated on 13 May 2019, but it was inadequate.

Observation 4: Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

a. Your firm did not have a formal complaint handling procedure reviewed and approved by the Quality Unit. No CAPA was initiated.

Verbal Observation 1:
Refrigerator (b)(4) stored USP References used to execute HPLC assays. This Refrigerator was not qualified and mapped. No CAPA/Deviation was opened.

Verbal Observation 2:
Standard Operating Procedure, SOP-1005.00, "Handling Deviations & CAPA" needed clarity on how System Suitability failures occurring in the HPLC are to be resolved. No CAPA/Deviation was opened.

2. SOP-1008, Supplier Approval Program, v2.0 states in part that the purpose of the SOP is to "describe the general practices required for assessing, reviewing, and approving suppliers of GMP materials and/or services.
   a. Your firm failed to qualify the suppliers of the following HPLC Columns used in your analytical testing of GMP drug product:
      i. HPLC column (b)(4) used in (b)(4), Assay and Related Substances for (b)(4) by HPLC, Protocol (b)(4). Your firm used this method to determine (b)(4) HCl assay and related substances in (b)(4) stability timepoint.

      ii. HPLC Column (b)(4), Column # 008MA-04723M used in Method (b)(4)-HPLC (b)(4) Aggregate Quantification (b)(4). Your firm used this method to quantify the percentage of higher and lower molecular weight species in (b)(4) Drug Substance (DS) and Drug Product (DP).

      iii. HPLC Column (b)(4), Column # 008MA-10557K used in Protocol, (b)(4) BRD Stability Testing (b)(4) Active Drug Product- (b)(4). Your firm used this method to perform GMP lot release (time (b)(4) testing of (b)(4) active drug product (DP) pre-filled syringes and place into stability chambers at specified conditions for testing at (b)(4), and (b)(4) per proposal # 2423.

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iv. HPLC Column (b)(4), Part No. (b)(4) used in Method (b)(4) HPLC for (b)(4) . Your firm used this method to (b)(4) drug substance (OS) and drug product (DP) for expiration extension.

b. Your firm also failed to qualify suppliers of (b)(4) used for long or short term storage of your HPLC Columns referenced in Observation 1a.

c. Your firm's SOP-1008, Supplier Approval Program, v2.0 fails to define supplier audit frequency relative to supplier risk level.

3. Your SOP-1006, Out of Specification, v2.0. fails to govern retesting performed during out of specification (OOS) Phase 2 investigations. Method (b)(4) Assay and Related Substances for (b)(4) by HPLC, Protocol (b)(4) failed system suitability and was retested four times.

OBSERVATION 2

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,

1. Your firm failed to include a second verifier in the raw data reporting sections of the following executed methods for analytical testing of GMP drug product:
   a. (b)(4) Assay and Related Substances for (b)(4) by HPLC, Protocol (b)(4).

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b. (b)(4) Method Transfer Protocol for (b)(4) by (b) (4) Spectrophotometry.

c.Method (b)(4) HPLC for (b)(4)

d.Method (b)(4) -HPLC (b)(4) Aggregate Quantification (b)(4)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."