DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495 - 5100 Industry Information: www.fda.gov/oc/industry	03/23/2026 - 03/26/2026
	FEI NUMBER 3033031230

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael S. Scott, Quality Site Head

FIRM NAME	STREET ADDRESS
Fagron Analytical Services, LLC	8851 E. 34th Street N
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Wichita, KS 67226-2624	Contract 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) (WE) OBSERVED:

OBSERVATION 1

Failure to maintain a backup file of data entered into the computer or related system.

Specifically,

The Mettler Toledo pH meter used in the chemistry laboratory creates digital data and results that are not backed up. The instrument can store up to 250 results, but there is no system in place to preserve this electronic data before it is overwritten or lost.

Additionally, the pH meter does not have unique usernames and logins for individual operators. Instead, a shared username, "Analyst," is used by (b) (4) personnel. This shared login system does not allow for attribution of specific test results to individual operators and does not provide adequate controls to ensure that only authorized personnel are accessing and using the equipment.

There is no assurance that pH test data generated by this equipment is complete, accurate, and attributable to specific individuals, or that historical data can be retrieved for batch record review or investigation purposes.

The pH meter is used for release testing on the following products:

Product
(b) (4)

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	ERIC D. BOWLES -S Digitally signed by ERIC D. BOWLES -S Date: 2026.03.26 13:43:56 -05'00' CHAD W. RICE -S Digitally signed by CHAD W. RICE -S Date: 2026.03.26 13:39:33 -05'00'	Eric D. Bowles, Investigator Chad W. Rice Investigator	03/26/2026