DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of New Drug Study Integrity Office of Study Integrity and Surveillance USFDA-CDER WO 22, Room 5224, 10903 New Hampshire Ave Silver Spring, MD 20993, USA Tel: 301-796-0459 Industry Information: www.fda.gov/oc/industry	10/20/2025 to 10/24/2025 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Edith Romp, Executive Director, Bioanalytical Services

FIRM NAME	STREET ADDRESS
ICON plc	Amerikaweg 18
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
9407 TK Assen, Drenthe, Netherlands	Bioanalytical Facility

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:

The following observation pertaining to method validation activities for (b) (4) and (b) (4) (method validations # JJP130EL-151303-B, JJP1953A-1953AX-A and JJP20016-20016X-B):

The site did not evaluate the method's specificity for (b) (4) and (b) (4) in the presence of all co-administered medications during bioanalytical method validation. Specifically, the method's specificity for (b) (4) and (b) (4) was only evaluated in the presence of paracetamol; however, some subjects also received cetirizine, desogestrel, ethinyl estradiol, drospirenone, ethinylestradiol betadex clathrate, levonorgestrel, and medroxyprogesterone acetate during the study. The method's specificity in the presence of these additional medications was not evaluated.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	SRI RAMA YELLELA -S Digitally signed by SRI RAMA YELLELA -S Date: 2025.10.24 10:56:42 -04'00'	Sri Rama Krishnaiah Yellela, Ph.D. Pharmacologist	10/24/2025

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 judgement, 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."