

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

CDER/OPQ/OPMA/DBM, Attn: Zhihao Peter Qiu, Ph.D., Director  
10903 New Hampshire Avenue; White Oak Building 22, Room 5112  
Silver Spring, MD 20993  
E-mail: OPFBLAinspection483Responses@fda.hhs.gov

DATE(S) OF INSPECTION

04/26/2021-04/30/2021

FEI NUMBER

3007029098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Lorraine Brophy, Ph.D., Site Quality Head

FIRM NAME

Janssen Sciences Ireland UC

STREET ADDRESS

Barnahely

CITY, STATE, ZIP CODE, COUNTRY

Ringaskiddy, Co. Cork, Ireland, P43 FA46

TYPE ESTABLISHMENT INSPECTED

Drug Substance 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 invalid assays are not adequately investigated. Although SOPs for Management of Laboratory Issues in the GMP Analytical and Microbiological Laboratories (TV-SOP-42841) and Handling of Invalid Assays and Laboratory Quality Investigations (TV-WI-42556) dictate further investigation of all invalid assay rates > (b) (4)%, adequate investigations or corrective actions were not implemented.

Specifically,

- a. The (b) (4) invalid rate for the (b) (4) assay was (b) (4)% (TV-TEC-179294 (b) (4) Invalid Assay Trend Report for JSI QC Cork (b) (4) v 1.0, approved on 30 July 2020).
- b. The (b) (4) assay invalid rates were (b) (4) for (b) (4) (b) (4) Bioassay rates were reported as (b) (4) in (b) (4) (TV-TEC-187892 (b) (4) Invalid Assay Trend Report for JSI QC Cork (b) (4) v 1.0 approved on 13 April 2021).
- c. The (b) (4) assay invalid rate was (b) (4)% for (b) (4) QI 1965156 was raised on 4/28/2021. (TV-TEC-200075 (b) (4) Invalid Assay Trend Report for JSI QC Cork (b) (4) to (b) (4) v 1.0 approved on 29 April 2021)

SEE  
REVERSE  
OF THIS  
PAGE

EMPLOYEE(S) SIGNATURE

Madushini N. Dharmasena -S

Sarah Johnson -S

Digitally signed by Madushini N. Dharmasena -S  
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA,  
ou=People, cn=Sarah Johnson -S,  
0.9.2342.19200300.100.1.1=0013396850  
Date: 2021.04.30 04:54:26 -0400

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ou=People, cn=Sarah Johnson -S,  
0.9.2342.19200300.100.1.1=0013396850  
Date: 2021.04.30 04:54:26 -0400

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Madushini Dharmasena, Ph.D., SR  
PHARMA. QUALITY ASSESSOR

Sarah Johnson, Ph.D., BIOLOGIST

DATE ISSUED

04/30/2021