DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	May 12th - 20th, 2026 FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Ariff Khan BJ, Executive Vice President	
FIRM NAME Strides Pharma Science Ltd.	STREET ADDRESS KRS Gardens, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk,
CITY, STATE, ZIP CODE, COUNTRY Bangalore, Karnataka, 562106, India	TYPE ESTABLISHMENT INSPECTED Human Drug 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:

OBSERVATION 1

Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically,

A. Your microbiological identification method used for confirmatory identification of (b) (4) (b) (4) and other specified microorganisms in finished drug products, raw materials, and (b) (4) has not been validated or verified for its intended use. Your firm uses the (b) (4) microbial identification system (b) (4) System) for confirmatory identification of microorganisms; however, you have not qualified the (b) (4) System to identify all organisms routinely tested as part of your firm's microbial limit testing (MLT) including:

A.1. Your firm's (b) (4) testing procedure requires (b) (4) testing for (b) (4) and subsequent confirmatory identification on positive samples using the (b) (4) System. During the inspection, all (b) (4)

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of your (b) (4) sampling (b) (4) loops (b) (4) sampled on (b) (4) were found positive for (b) (4) on (b) (4) on (b) (4) and were processed for confirmatory identification using an unvalidated test method on the (b) (4) System which is not qualified to detect (b) (4) from this (b) (4) system (b) (4) is used for the production of US products including (b) (4)

A.2. Your firm's microbial limit test specifications and batch release records confirm that (b) (4) (b) (4) is a routinely required specified organism test for multiple finished drug products, including but not limited to:

(b) (4)

Your firm's PQ documentation acknowledges that (b) (4) is absent from the standard PQ organism panel (Table (b) (4) and that the system's ability to identify this organism is dependent on its inclusion in the (b) (4) software knowledge base, which has not been verified or documented by your firm. No supplemental qualification study, challenge testing, or vendor confirmation has been provided to demonstrate that the (b) (4) system is capable of reliably identifying (b) (4) isolates recovered during routine testing.

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A.3. Your firm uses the (b) (4) (b) (4) system for confirmatory identification of microorganisms including (b) (4) identified from your (b) (4) (b) (4) system, and (b) (4) (b) (4) in raw materials, using methods that are not validated or verified, and your (b) (4) system is not qualified to detect these microorganisms. Your firm's initial performance qualification of the (b) (4) (b) (4) system was carried out using (b) (4) organisms — (b) (4) (b) (4); and does not reflect the full panel of organisms your (b) (4) system is used to identify across (b) (4) systems, finished products, and raw materials.

B. During the inspection on (b) (4) your test results for Total Aerobic Microbial Count (TAMC) for (b) (4) sampled on (b) (4) on (b) (4) loop (b) (4) of the (b) (4) system, showed a colony count of (b) (4) CFU (b) (4) mL on (b) (4), which was identified as exceeding both the alert and action limits. Your SOP GQC/072/R6, effective May 31, 2023, titled "Microbial Enumeration Tests and Tests for Specified Microorganisms," indicates in Section (b) (4) that a colony count above (b) (4) CFU on (b) (4) is to be considered Too Numerous To Count (TNTC), which, per your procedures, requires an Out of Specification (OOS) investigation. Your firm has not had any microbiological OOS investigation in the last 3 years. Your management stated that, as individual colonies can be counted, the result is reported as (b) (4) CFU (b) (4) mL (b) (4) CFU/mL) and not as TNTC; however, your firm has not verified or established, through validation or documented justification, the upper countable colony limit for the (b) (4) method beyond the (b) (4) CFU threshold defined in your SOP.

C. Your firm's quality control analysts (User Type 2 – F1_Analyst) have been granted the "Modify Processing Method" privilege within the Chromeleon 7.3.2 Chromatography Data System, allowing them

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to alter peak integration parameters and detection settings while simultaneously viewing recalculated numerical results — including peak area counts — in the Data Processing window of the Chromatography Studio, without requiring the processing method changes to be saved prior to viewing updated chromatographic results. The software automatically renders recalculated peak area results in real time during unsaved "Pending Modifications" edits. This functionality enables analysts to repeatedly view the numerical impact of processing method modifications on peak area results before saving the changes and committing them to the audit trail. This creates an opportunity to select favorable integration outcomes without generating a complete and contemporaneous audit trail record of all parameter iterations evaluated.

The User Privilege Matrix (Document No. FI/QC/UP/CHR.7.3.2/R3) confirms that the compensating controls "Modify Processing Method – Restricted" and "Modify Processing Method – Custom" — which would limit the scope of editable parameters through a Ruleset — have not been enabled for the User Type 2-F1_Analyst role. Using this configuration, your firm has tested at least (b) (4) batches of finished drug products, including (b) (4) drugs such as (b) (4) (b) (4) for assay and related substance testing by HPLC over the past 27 months (January 2023 through March 2026).

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OBSERVATION 2

All records of production associated with a batch of drug product were not maintained at least one (1) year after the expiration date.

Specifically,

Your firm failed to retain electronic audit trail data generated by manufacturing equipment for the required period, failed to establish procedures for the review of audit trail data, and failed to ensure that audit trail review results in investigation of manufacturing anomalies.

A. Electronic audit trail data for all (b) (4) and some (b) (4) equipment is permanently deleted after one year. Drug products manufactured on these machines carry a typical shelf life of (b) (4) (b) (4) As a result, audit trail data is being destroyed while product manufactured on these machines remains on the U.S. market within its expiration date. There is no assurance that the complete manufacturing history for distributed drug product lots can be reconstructed or verified. Approximately (b) (4) batches of drug products have been manufactured using these pieces of equipment since 2024, with audit trail data permanently deleted while products remain within expiry on the U.S. market. Examples include but are not limited to:

Finished goods Code	Product name	Mfg. Batch no	Mfg. Date	Exp Date	Shelf Life in (b) (4)	Final Dest.
(b) (4)						

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(b) (4)

B. Audit trail review for (b) (4) equipment is performed by viewing data on the Human Machine Interface (HMI) display without generating a printed or otherwise durable record of the review. No retrievable evidence exists of what the audit trail contained at the time of review or whether the review was sufficient to detect anomalies. Furthermore, this data is permanently deleted from the system after one year.

C. Your firm's audit trail review procedure does not define a limit on the number of times equipment parameters may be changed during batch processing, nor does it establish a threshold of repeated parameter changes that would require investigation or deviation initiation. As a result, reviewers have no documented standard against which to evaluate whether a pattern of parameter changes during manufacture of drug products constitutes an anomaly requiring investigation.

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D. A single audit trail review procedure and checklist are applied to all manufacturing equipment despite fundamentally different audit trail formats, event types, parameter designations, and alarm structures across equipment types. This approach does not provide assurance that reviewers are evaluating the data elements most critical to each equipment type and does not ensure that effective review is occurring.

OBSERVATION 3

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

A. (b)(4) | Equipment ID: (b)(4) | (b)(4) Manufacturing Suite)
On May 13, 2026, during the inspection of the (b)(4) Manufacturing Suite (b)(4) — Tablet Block, (b)(4) residues were observed on the (b)(4) of the (b)(4) (Equipment ID: (b)(4) following a Non-Serial Changeover (NSCO) — product-to-product cleaning — after the manufacture of (b)(4) Capsules (b)(4) mg (Batch No: (b)(4) with the equipment status label indicating "Cleaned." Your firm's Work Instruction No. F1/WI/PT/103/R2, titled "Operation and Cleaning of (b)(4) " (Section (b)(4) — Non-Serial Cleaning), requires complete dismantling of all components including the (b)(4) (b)(4) until no traces of previous product are observed, (b)(4) and IPQA verification of cleanliness in dismantled condition prior to reassembly and use, as documented in Cleaning Checklist F1/WI/PT/103/F-01/R1.

B. (b)(4) | Equipment ID: (b)(4) | (b)(4) Tablet Block
On May 13, 2026, during the inspection of the (b)(4) area of the Tablet Block, (b)(4) residues were observed on top of the HEPA filter housing located on the technical floor (b)(4) unit of the

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(b) (4) (Equipment ID: (b) (4) These residues were identified following the manufacture of the previous product, (b) (4) and prior to the commencement of manufacturing for the next product, (b) (4) (intended for the US market and Rest of World). Residues identified in the (b) (4) unit area present a potential risk of cross-contamination, as particulates in this zone may be reintroduced into the processing environment during subsequent manufacturing operations, particularly during the transition between two distinct drug products.

C. (b) (4) Equipment | Equipment ID: (b) (4) Block, (b) (4) (b) (4) Area

On May 12, 2026, during the inspection of the (b) (4) area (b) (4) of the (b) (4) Block, more than (b) (4) capsules from the previous batch of (b) (4) Capsules (b) (4) mg (Batch No: (b) (4) were observed remaining on the manufacturing line during a Serial Changeover (SCO) — batch-to-batch cleaning — including on the conveyor, chute assembly (b) (4), and tubing connecting line components. This is contrary to your firm's Work Instruction No. F1/WI/PS/016/R5, titled "Dismantling, Cleaning, Line Clearance, Assembling and Start Up of (b) (4) Machine" (effective May 31, 2025), Sections (b) (4) through (b) (4) which require complete removal of all previous batch capsules from the chute assembly (b) (4), conveyor, and (b) (4) emptying of the (b) (4), and complete removal of product from the (b) (4) tubing prior to commencement of the subsequent batch, with IPQA verification documented in Cleaning Checklist F1/WI/PS/016/F-01/R5. This equipment is also used in the manufacture of US-marketed products including (b) (4) (b) (4) capsules.

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OBSERVATION 4

Your firm failed to exercise controls over computerized manufacturing equipment to ensure that only authorized personnel can create and modify recipes, that obsolete or unauthorized recipes cannot be selected for commercial manufacturing, and that accurate data input is maintained across your facility's computerized systems.

Specifically,

A. Multiple obsolete and unauthorized recipes exist simultaneously on (b) (4) equipment with no functional mechanism to prevent their selection during commercial manufacturing. Obsolete and unauthorized recipes were observed on the following equipment: (b) (4) (b) (4) (b) (4) Your firm acknowledges that obsolete recipes cannot be deleted from equipment due to system limitations. These obsolete recipes remain accessible to production supervisors during batch manufacturing, creating risk for incorrect recipe selection across multiple product lines and manufacturing areas.

For example, your (b) (4) equipment (b) (4) used for manufacturing (b) (4) (b) (4) tablets contains numerous obsolete recipes for the same product code (b) (4) including versions (b) (4) that are marked obsolete but remain selectable on the Human Machine Interface (HMI) for (b) (4) Additionally, other equipment, such as (b) (4) contains numerous unauthorized recipes that are selectable during commercial production, including recipes named after specific batches such as (b) (4) (b) (4) Your firm's procedures acknowledge this limitation but do not provide compensating controls to prevent incorrect recipe selection during manufacture of commercial

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batches. (b) (4) machine (b) (4) was recently used to manufacture (b) (4) (b) (4) tab (b) (4) mg batches (b) (4) This product was shipped for distribution to the US market (b) (4)

B. Inadequate Access Controls and User Privilege Management

Your user access system combines Quality Assurance personnel with production supervisors under a single user category. Your procedures state that recipe creation should be restricted to Quality Assurance personnel, yet the combined user access structure grants both production supervisors and Quality Assurance personnel identical system privileges on computerized equipment. This arrangement fails to enforce the intended segregation of duties and allows production personnel to perform recipe management functions that should be restricted to Quality Assurance oversight.

C. Inadequate Documentation and Verification

Your batch manufacturing records fail to consistently document which specific recipes were used during manufacturing operations across your computerized systems. While some equipment operations clearly identify recipe names, other operations show parameter controls without documenting the specific recipe selected from multiple available options.

For example, batch (b) (4) tablets (b) (4) mg) manufactured using recipe-capable (b) (4) equipment (b) (4) fails to identify which specific recipe was selected from multiple available options. In contrast, batches manufactured using non-recipe (b) (4) equipment demonstrate manual parameter documentation including lot-by-lot parameter tables with specific limits and parameter verification comparing set versus recorded values.

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Additionally, your firm lacks dedicated procedures for recipe lifecycle management, with recipe control embedded within broader manufacturing procedures rather than treated as a critical control system requiring comprehensive documentation and controls. This deficiency affects multiple manufacturing areas and equipment types throughout your facility.

OBSERVATION 5

Each component is not tested for conformity with all written specifications for purity, strength, and quality.

Specifically,
Your firm failed to perform (b) (4) testing, including the limit test for (b) (4) (b) (4) (NMT (b) (4) %), on (b) (4) each shipment of each lot of high-risk drug components prior to their use in manufacturing drug products distributed to the United States market. SOP GQC/022/R09, effective (b) (4), mandated (b) (4) testing for (b) (4) in high-risk components. Despite this requirement, the firm's practice, both before and after the SOP effective date, was to test only (b) (4) sample rather than (b) (4) (b) (4) testing results were not recorded in the firm's LIMS. This failure was not detected by the firm's quality system for the following raw materials:

A. (b) (4) USP (Material Code (b) (4) (b) (4) testing for (b) (4) was not performed on lots of (b) (4) USP received prior to (b) (4), despite the applicable FDA guidance having been issued in (b) (4) — representing a gap of approximately (b) (4) Furthermore, this failure continued after the SOP effective date: lot (b) (4) received after (b) (4), was tested by (b) (4) sample only;

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(b) (4) were not tested as required. There is no assurance that (b) (4) of (b) (4) USP used in manufacturing are free from (b) (4) contamination above safety limits. (b) (4) USP is used in the manufacture of (b) (4) Capsules USP (b) (4) (b) (4) mg, (b) (4) distributed to the US market.

Examples of finished drug product batches manufactured using (b) (4) USP lot (b) (4) and distributed to the US market include, but are not limited to:

Batch No.	Product	Mfg. Date	Exp Date	Ship Date
(b) (4)				

Approximately (b) (4) finished drug product batches were released to the US market during the period in which (b) (4) testing was not performed. Approximately (b) (4) batches remain within expiry, with the latest expiry date (b) (4)

B. (b) (4) USP (Material Code (b) (4) : (b) (4) testing for (b) (4) was not performed on lots of (b) (4) USP received prior to (b) (4) representing a gap of approximately (b) (4) from the date of the FDA guidance. Furthermore, this failure continued after the SOP effective date: lot (b) (4) received after (b) (4) was tested by (b) (4) sample only: (b) (4)

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were not tested as required. (b) (4) USP is used in the manufacture of multiple drug products distributed to the US market, including (b) (4) (b) (4)

Examples of finished drug product batches manufactured using (b) (4) USP lot (b) (4) (pre-SOP) and distributed to the US market include, but are not limited to:

Batch No	Product	Mfg. Date	Exp Date	Ship Date
(b) (4)				

Examples of finished drug product batches manufactured using (b) (4) USP lot (b) (4) (pre-SOP) and distributed to the US market include, but are not limited to:

Batch No	Product	Mfg. Date	Exp Date	Ship Date
(b) (4)				

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(b) (4)

Additional lots of (b) (4) USP for which (b) (4) testing was not performed include: (b) (4) (b) (4) Approximately (b) (4) finished drug product batches were released to the US market without complete (b) (4) testing data. Approximately (b) (4) batches remain within expiry, with the latest expiry date of (b) (4)

C. (b) (4) USP (Material Code (b) (4)
Although your procedure mandated (b) (4) testing effective (b) (4) the (b) (4) (Limit of (b) (4) was not formally incorporated into the raw material specification (b) (4) RMS) until (b) (4) via Change Control PC-ODF/2024/843 approximately (b) (4) after the SOP requirement became effective. During this interval, the controlling specification document did not require the (b) (4) test, creating a gap between procedural requirements and the formal specification. (b) (4) USP is used in the manufacture of (b) (4) Capsules USP (b) (4) mg, (b) (4) distributed to the US market.

Examples of finished drug product batches manufactured using (b) (4) USP lot (b) (4) and distributed to the US market include, but are not limited to:

Batch No	Product	Mfg. Date	Exp Date	Ship Date
(b) (4)				

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		
	Lisa L. Flores, Investigator	LLF	May 20th 2026
	Rafeeq A. Habeeb, Investigator	RAH	
	Constance Richard Math, Supervisory Investigator	CLRM	

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	May 12th - 20th, 2026 FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Ariff Khan BJ, Executive Vice President	
FIRM NAME Strides Pharma Science Ltd.	STREET ADDRESS KRS Gardens, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk,
CITY, STATE, ZIP CODE, COUNTRY Bangalore, Karnataka, 562106, India	TYPE ESTABLISHMENT INSPECTED Human Drug Manufacturer

(b) (4) [redacted]

Examples of finished drug product batches manufactured using (b) (4) [redacted] USP lot (b) (4) [redacted] and distributed to the US market include, but are not limited to:

Batch No.	Product	Mfg. Date	Exp Date	Ship Date
(b) (4) [redacted]				

Additional lots of (b) (4) [redacted] USP for which (b) (4) [redacted] testing was not performed include: (b) (4) [redacted] Approximately (b) (4) [redacted] finished drug product batches were released to the US market without complete (b) (4) [redacted] testing data. Approximately (b) (4) [redacted] batches remain within expiry, with the latest expiry date of (b) (4) [redacted]

D. (b) (4) [redacted] USP (Material Code (b) (4) [redacted]
Your firm failed to perform (b) (4) [redacted] testing for the (b) (4) [redacted] limit (b) (4) [redacted] NMT (b) (4) [redacted] %) on lots (b) (4) [redacted] USP, including lots received after the SOP effective date of (b) (4) [redacted] (including AR Nos (b) (4) [redacted] As with other high-risk components, the firm's practice was to test (b) (4) [redacted] sample only; (b) (4) [redacted] results were not obtained or recorded. This failure was not detected by the firm's quality system and was identified during this inspection. (b) (4) [redacted] USP is used in the manufacture of multiple drug products distributed to

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	Constance Richard Math, Supervisory Investigator	CLRM	

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CITY, STATE, ZIP CODE, COUNTRY Bangalore, Karnataka, 562106, India	TYPE ESTABLISHMENT INSPECTED Human Drug Manufacturer

the US market, including (b) (4)

(b) (4)

Examples of finished drug product batches manufactured using (b) (4) USP lot (b) (4) and distributed to the US market include, but are not limited to:

Batch No.	Product	Mfg. Date	Exp Date	Ship Date
(b) (4)				

Examples of finished drug product batches manufactured using (b) (4) USP lot (b) (4) and distributed to the US market include, but are not limited to:

Batch No.	Product	Mfg. Date	Exp Date	Ship Date
(b) (4)				

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	Rafeeq A. Habeeb, Investigator	RAH	
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	May 12th - 20th, 2026 FEI NUMBER 3004554612

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Ariff Khan BJ, Executive Vice President	
FIRM NAME	**STREET ADDRESS**
Strides Pharma Science Ltd.	KRS Gardens, Suragajakkanahalli, Indlawadi Cross, Anekal Taluk,
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Bangalore, Karnataka, 562106, India	Human Drug Manufacturer

Additional lots of (b) (4) USP for which (b) (4) testing was not performed include: (b) (4) Approximately (b) (4) finished drug product batches were released to the US market without complete (b) (4) testing data. Approximately (b) (4) batches remain within expiry, with the latest expiry date of (b) (4)

	EMPLOYEE(S) SIGNATURE		
SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Constance Richard Math, Supervisory Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2026.05.20 10:30:14 +05'30' RAFEEQ HABEEB -S Digitally signed by RAFEEQ HABEEB -S Date: 2026.05.20 10:32:57 +05'30' Constance L. Richard-math -S Digitally signed by Constance L. Richard-math -S Date: 2026.05.20 10:27:51 +05'30'	May 20th 2026