DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/16/2026
	FEI NUMBER 3001413302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind Singh, Factory Manager

FIRM NAME	STREET ADDRESS
Dabur India Limited	225 - 4 - 1 Saily Village, Survey No
CITY, STATE, ZIP CODE, COUNTRY Dadra And Nagar Haveli, Dadra And Nagar Haveli And Dam, 396240 India	TYPE ESTABLISHMENT INSPECTED OTC 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 I OBSERVED:

OBSERVATION 1

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

During the inspection, your firm's laboratory operations were found to have significant deficiencies in data integrity, record maintenance, and analytical controls. Your quality control unit did not adequately oversee these operations to prevent systematic violations. Specifically:

A) Inaccurate Laboratory Data: Review of records of over (b) (4) finished product microbiology samples tested over (b) (4) revealed that 100% of the results were reported as "<10" (zero colonies) in laboratory records. However, during the inspection on January 12, 2026, investigator observed the presence of colonies on multiple plates during plate reading activities including two plates that were TNTC (too numerous to count) for the drug product (b) (4) (b) (4) which was inconsistent with the documented trend. Your firm performs microbial release testing for US marketed OTC products including (b) (4) (b) (4) Additionally, (b) (4) testing data exhibited repetitive number patterns for duplicate microbial (b) (4) testing plates (example CFUs: (b) (4) (b) (4) that suggest the data may not reflect actual analytical test results. Your facility uses (b) (4) as a component in drug products, including (b) (4) and multiple (b) (4) as well as for cleaning of manufacturing equipment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 01-16-2026 18:29:13	1/16/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/16/2026
	FEI NUMBER 3001413302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind Singh, Factory Manager	
FIRM NAME Dabur India Limited	STREET ADDRESS 225 - 4 - 1 Saily Village, Survey No
CITY, STATE, ZIP CODE, COUNTRY Dadra And Nagar Haveli, Dadra And Nagar Haveli And Dam, 396240 India	TYPE ESTABLISHMENT INSPECTED OTC Manufacturer

B) Missing Physical Evidence and Documentation: During the inspection on January 12, 2026 multiple finished product (approximately (b) (4) plates from (b) (4) and (b) (4) testing plates (approximately (b) (4) plates from (b) (4) documented in analytical data notebooks scheduled for reading s, with no documentation explaining their disposal or location. Your firm failed to create and maintain sample receipt logs for both finished product microbiology samples and (b) (4) microbiology samples, preventing verification of sample chain of custody and testing timelines.

C) Inadequate Laboratory Controls: Microbiology colony counting for finished product testing is performed by a single person without second person verification, creating single-point control over critical testing operations. Additionally, growth promotion testing is performed only once upon (b) (4) media receipt rather than for each lot or batch of prepared media used in testing, which does not ensure continued media viability throughout its use period.

D) Quality Control Unit Oversight Deficiencies: Your quality control unit failed to identify and investigate the complete absence of microbiological assay out-of-specification (OOS) results over the past five years, did not establish adequate analytical procedures and controls, and did not detect systematic data integrity issues, indicating inadequate quality oversight responsibilities.

E) Inaccurate Production Records: During the inspection on January 15, 2026, your firm falsified critical manufacturing records by creating fraudulent equipment usage documentation designed to conceal multi-product manufacturing operations. This equipment usage documentation was created for the (b) (4) utilized in the manufacturing of (b) (4) (b) (4) covering the period from April 2024 to December 2025. The newly created equipment log deliberately removed several US products recorded in the original equipment logbook, including (b) (4) (b) (4) Review of the original

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 01-16-2026 18:29:13	1/16/2026

equipment logbook revealed that the (b) (4) had been used for manufacturing multiple products, including (b) (4) and other over-the-counter (OTC) products, which is inconsistent with your firm's initial representation that this equipment is dedicated exclusively for (b) (4) production. The preparation of documentation that excludes recorded product usage information does not ensure complete and accurate equipment records necessary for proper manufacturing controls and equipment identification, compromises the integrity and completeness of required manufacturing documentation, and contradicts the principle of contemporaneous recording of manufacturing activities as they occur. You do not have a risk assessment for manufacturing multiple products in Unit (b) (4) Line (b) (4)

F) **Inadequate documentation controls and failure to investigate discrepancies in finished product testing program**: Specifically, on [January 13 to 15, 2026], the following deficiencies were observed in your (b) (4) testing program for finished products: inspection results were initially recorded on loose, uncontrolled papers before being transferred into official log notebooks. The actual number of product boxes opened and tested were falsified claiming more product units were tested than were sampled. In addition, your firm failed to initiate required deviation investigations or non-conformance reports after discovering critical product defects including empty (b) (4) and coding errors on multiple instances.

OBSERVATION 2

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically, your cleaning validation program for non-dedicated manufacturing equipment, used for multiple drug products, is inadequate.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/16/2026
	FEI NUMBER 3001413302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind Singh, Factory Manager	
FIRM NAME Dabur India Limited	STREET ADDRESS 225 - 4 - 1 Saily Village, Survey No
CITY, STATE, ZIP CODE, COUNTRY Dadra And Nagar Haveli, Dadra And Nagar Haveli And Dam, 396240 India	TYPE ESTABLISHMENT INSPECTED OTC Manufacturer

A) Your cleaning validation for Line (b) (4) Unit (b) (4) which manufactures (b) (4) multiple (b) (4) (b) (4) is inadequate for the following including. The analytical methodology relies exclusively on visual inspection of (b) (4) samples, which is scientifically inadequate as it cannot detect residues or contamination below visible thresholds. The acceptance criteria are limited to visual appearance standards without establishing scientifically justified maximum allowable carryover limits, quantitative residual limits in parts per million, or microbiological cleanliness standards. The sampling strategy involves collection of (b) (4) from (b) (4) points and does not include direct surface sampling from equipment contact surfaces, difficult-to-clean areas, complex geometries, or representative sampling of all product contact surfaces. Line (b) (4) manufactures (b) (4) OTC products including (b) (4) (b) (4) (b) (4) The combination of (b) (4) (b) (4) creates a complex manufacturing environment requiring stringent cleaning validation protocols between all product changeovers to prevent unintended ingredient transfer and potential adverse reactions. The worst-case evaluation is similarly insufficient, identifying (b) (4) as the worst case based solely on (b) (4) considerations without evaluating critical factors such as (b) (4) characteristics, (b) (4) properties, (b) (4), or conducting a comprehensive cross-contamination risk assessment. In the last 3 years you firm has manufacture approximately (b) (4) batches of OTC products in Line (b) (4) Unit (b) (4)

B) Line (b) (4) Unit (b) (4) falsely represented as dedicated exclusively to (b) (4) manufacturing, has been used for multi-product manufacturing operations without any cleaning validation whatsoever. This deliberate misrepresentation of equipment dedication, combined with the complete absence of cleaning validation, represents a product carryover concern affecting more than (b) (4) batches of (b) (4) OTC pharmaceutical products manufactured over the previous three years and still within expiry.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 01-16-2026 18:29:13	1/16/2026

C) The cleaning validation approach for Line (b) (4) Unit (b) (4) represents a fundamental failure of pharmaceutical validation science due to inappropriate extrapolation of insufficient data across multiple production lines. Your firm conducted validation testing on only one production line using a single product (b) (4) with results from (b) (4) cleaning cycles yet extrapolated these findings without sufficient scientific justification to justify cleaning validation for (b) (4) non-dedicated lines manufacturing different (b) (4) products with varying formulations, equipment configurations, and cleaning challenges. Your firm has manufactured approximately (b) (4) batches of (b) (4) OTC products in Unit (b) (4) Lines (b) (4) in the past 3 years.

OBSERVATION 3

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

During the inspection, batch manufacturing and analytical records for (b) batches across (b) products were reviewed: (b) (4) The following deficiencies were observed:

A) Analytical data for residue on ignition and melting range tests recorded in BMRs and COAs did not match the corresponding entries in (b) (4) analytical data books for (b) (4)

batches (b) (4) Similarly, pH and viscosity test data discrepancies were found for (b) (4) batches (b) (4)

B) No standard testing procedures, analytical workbooks, or test sheets were available to support finished product analytical results reported in COAs for critical tests including residue on ignition and melting point determinations. Your firm has manufactured and released approximately (b) (4) batches of (b) (4) (b) (4) in the last 3 years without documented analytical data and records.

C) For (b) (4) batch (b) (4) assay values for (b) (4) were interchanged between the third-party COA and your firm's COA. The subsequently provided corrected vendor COA retained identical certificate details (certificate number and date of issuance) with only values corrected, lacking documentation for the investigation or acknowledgment of the original error.

D) Equipment logbook entries were missing for: (b) (4) usage during residue on ignition testing of (b) (4) batch (b) (4) melting point apparatus usage during melting point testing of (b) (4) batch (b) (4) pH meter usage during pH testing of (b) (4) batch (b) (4) and viscometer usage during viscosity testing of (b) (4) (b) (4) batches (b) (4)

E) Critical process parameters, including processing (b) (4) were not recorded in BMRs for (b) (4) batches (b) (4)

F) The BMR for (b) (4) batch (b) (4) incorrectly documented the API quantity used as (b) (4) instead of the actual dispensed amount of (b) (4) as specified in the Bill of Materials.

G) Equipment identification numbers for the (b) (4) were not recorded in the BMR for

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/16/2026
	FEI NUMBER 3001413302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind Singh, Factory Manager

FIRM NAME	STREET ADDRESS
Dabur India Limited	225 - 4 - 1 Saily Village, Survey No
CITY, STATE, ZIP CODE, COUNTRY Dadra And Nagar Haveli, Dadra And Nagar Haveli And Dam, 396240 India	TYPE ESTABLISHMENT INSPECTED OTC Manufacturer

(b) (4) batch (b) (4) used in manufacturing (b) (4) batch (b) (4)

H) Signatures by chemist was not recorded in the Annexure I "Cleaning and Sanitation of product contact parts of filling machine" for (b) (4) batch (b) (4) and in process test data was not reviewed and/or signed by Chemist and QA for (b) (4) batch (b) (4) and the batch was released for filling.

OBSERVATION 4

Written procedures are not established and followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Specifically, during the inspection, it was observed that your firm has not conducted Annual Product Quality Reviews (APQRs) for the majority of products manufactured at (b) (4) manufacturing units. While your firm provided APQRs for (b) (4) numerous other OTC drug products manufactured during the review period lack APQRs. Based on batch records reviewed, products missing APQRs include various (b) (4) products manufactured at Unit (b) (4) Your firm's own SOP APQR (SOP/QA/014-06, Section 8.5) acknowledges this requirement, stating "Annual Product Quality Review shall be prepared for all products which are in the market (b) (4)."

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 01-16-2026 18:29:13	1/16/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/16/2026
	FEI NUMBER 3001413302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind Singh, Factory Manager

FIRM NAME	STREET ADDRESS
Dabur India Limited	225 - 4 - 1 Saily Village, Survey No
CITY, STATE, ZIP CODE, COUNTRY Dadra And Nagar Haveli, Dadra And Nagar Haveli And Dam, 396240 India	TYPE ESTABLISHMENT INSPECTED OTC Manufacturer

OBSERVATION 5

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin.

Specifically, during the inspection conducted on [01/15 and 01/16/2026], the following deficient conditions were observed: a live bird and bird droppings were found in the raw material warehouse, approximately 30 feet from (b) (4) packaging materials; apparent unidentified black substance was observed covering over 25% of the ceiling surfaces in both the raw material warehouse and finished drug product storage warehouse; and a gap approximately 1 inch was observed in the dock door of the finished product storage warehouse.

OBSERVATION 6

Equipment surfaces that contact components and in-process materials are reactive, additive or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Specifically, during the inspection conducted on [01/15 to16/2026], hoses connected to points of use in the Unit (b) (4) area and Unit (b) (4) manufacturing area were found to contain stagnant (b) (4) compromising (b) (4) quality and creating microbiological contamination risks. The (b) (4) in these hoses is used for cleaning (b) (4) tanks utilized in the manufacturing of drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 01-16-2026 18:29:13	1/16/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/16/2026
	FEI NUMBER 3001413302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Arvind Singh, Factory Manager

FIRM NAME	STREET ADDRESS
Dabur India Limited	225 - 4 - 1 Saily Village, Survey No
CITY, STATE, ZIP CODE, COUNTRY Dadra And Nagar Haveli, Dadra And Nagar Haveli And Dam, 396240 India	TYPE ESTABLISHMENT INSPECTED OTC Manufacturer

OBSERVATION 7

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A) Your firm failed to complete process validation studies for (b) (4) (b) (4) manufactured at (b) (4) as required by (b) (4)

B) Your firm lacks adequate controls over your stability testing program. Specifically, you do not maintain a complete inventory of stability samples under test nor establish procedures for reviewing stability data generated by (b) (4)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Rafeeq A Habeeb, Investigator

X Rafeeq A Habeeb
Investigator
Signed By: 2002600695
Date Signed: 01-16-2026
18:29:13

DATE ISSUED

1/16/2026