DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/29/2026-7/10/2026* FEI NUMBER 3011430551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. James P. Cangelosi, Owner/President

FIRM NAME	STREET ADDRESS
Brookfield Medical/Surgical Supplies, Inc.	60 Old New Milford Rd Ste 1b
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brookfield, CT 06804-2429	Outsourcing 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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm failed to adequately investigate Out-of-Specification (OOS) results for potency testing of sterile drug products manufactured during May 2024-June 2026. A review of deviation records revealed thirteen (13) OOS potency failures across multiple drug products and lots, indicates a recurring and systemic failure to maintain adequate process controls.

All OOS were reportedly attributed to the contract testing laboratory and resolved via retesting at the same lab.

Table below shows all the potency OOS:

Deviation #	Date Initiated	Type	Drug Product	Lot Number(s)	Close Date	Vials
DV24-051	September 19, 2024	OOS Potency	Triamcinolone Acetonide	091124-1	October 4, 2024	(b) (4)
DV25-053	April 3, 2025	OOS Potency	Morphine Sulfate	032625-1	April 9, 2025	
DV25-054	April 7, 2025	OOS	Methylprednisolon	033125-1	April 14,	

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		Potency	e Acetate		2025	
DV25-055	June 9, 2025	OOS Potency	Betamethasone Sodium Phosphate	060425-1	June 26, 2025	(b) (4)
DV25-056	July 3, 2025	OOS Potency	Triamcinolone Acetonide (3 lots)	062325-1 / 061725-1 / 062425-1	July 9, 2025	
DV25-058	September 29, 2025	OOS Potency	Betamethasone Sodium Phosphate	091225-1	October 20, 2025	
DV26-059	January 2, 2026	OOS Potency	Methylprednisolone Acetate	121725-1	January 7, 2026	
DV26-060	February 9, 2026	OOS Potency	Betamethasone Sodium Phosphate	012026-1	February 17, 2026	
DV26-061	February 9, 2026	OOS Potency	Betamethasone Sodium Phosphate	012326-1	February 26, 2026	
DV26-062	February 12, 2026	OOS Potency	Betamethasone Sodium Phosphate	012926-1	February 17, 2026	
DV26-065	June 5, 2026	OOS Potency	Triamcinolone Acetonide	051526-1	Confirmed OOS	
DV26-066	June 5, 2026	OOS Potency	Triamcinolone Acetonide	051826-1	June 11, 2026	
DV26-067	June 5, 2026	OOS Potency	Triamcinolone Acetonide	052026-1	June 11, 2026	

Thirteen (13) OOS potency deviations were recorded over a 26-month period (May 2024-June 2026). OOS potency failures were observed across four (4) distinct sterile drug products-Triamcinolone Acetonide, Betamethasone Sodium Phosphate, Methylprednisolone Acetate and, Morphine Sulfate.

Repeated failures were observed with the same product, for example: Betamethasone Sodium Phosphate exhibited four (4) separate OOS potency events (DV25-055, DV25-058, DV26-060, DV26-061, DV26-

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062), and Triamcinolone Acetonide exhibited four (4) events (DV24-051, DV25-056, DV26-065, DV26-066, DV26-067), suggesting that root cause analyses and corrective and preventive actions (CAPAs) were either inadequate or ineffectively implemented at the contract testing laboratory.

For DV25-058 (Betamethasone lot 091225-1). The contract testing laboratory stated the root cause was **undetermined**. However, the contract lab did not request a second sample to verify the results when no root cause was identified. Your firm did not conduct further investigation and released the batch.

All the compounded drug products were released for distribution after the initial result were invalidated except Triamcinolone Acetonide 3mL Lot number 051526-1 which was a confirmed out of specification potency result.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Your quality control unit failed to exercise adequate oversight of the contract testing laboratory performing potency testing (refer to the table in **Observation 1**) as evidenced by:

(1) Pattern of OOS invalidation without adequate QCU scrutiny

Thirteen (13) Out-of-Specification (OOS) potency results were recorded over 26 months between May 2024 and June 2026 across four drug products (Triamcinolone Acetonide, Betamethasone Sodium Phosphate, Methylprednisolone Acetate, and Morphine Sulfate).

Twelve (12) of these OOS results were invalidated and product was released without documented evidence that the quality control unit independently reviewed the contract laboratory's raw data, chromatograms, instrument logs and invalidation rationale.

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One result (Triamcinolone Acetonide 3mL, Lot 051526-1) was confirmed OOS, The QCU accepted the contract lab's invalidation conclusions in 12 of 13 cases without apparent independent verification.

For DV25-058 (Betamethasone lot 091225-1), the contract testing laboratory stated the root cause was **undetermined**. Your firm released the batch without any assignable cause of OOS and without initiating any CAPA.

2. Failure to question repeated OOS results from the same contract laboratory
Betamethasone Sodium Phosphate had 5 separate OOS events (DV25-055, DV25-058, DV26-060, DV26-061, DV26-062) - all tested by the same contract lab, and all apparently invalidated except as noted. QCU did not question the lab's analytical capability after recurring failures with the same product.

4. Rapid closure of deviations without thorough investigation and initiation of CAPA
Several deviations were opened and closed within days:
DV25-053: opened April 3, closed April 9 (6 days)
DV25-054: opened April 7, closed April 14 (7 days)
DV26-059: opened January 2, closed January 7 (5 days)
DV26-062: opened February 12, closed February 17 (5 days)

A 5-7-day turnaround for an OOS potency investigation involving a contract lab - including Phase I (lab investigation), Phase II (manufacturing investigation) is extremely compressed and indicates the QCU accepted results without conducting a thorough independent review.

5. Failure to audit or qualify the contract laboratory
The QCU did not audit the contract testing laboratory during the period in which 13 OOS results were generated.

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

The environmental monitoring program of your firm allows for a CFU limit (b) (4) for gloved fingertips in an ISO 5 area. For a CGMP compliant 503B facility, the action level must be any detected organism. Furthermore, your firm failed to investigate and identity the microbial growth recovered from the ISO 5 environment at the facility. All the compounded drug products were released for distribution.

The environmental monitoring (EM) excursion records below document nine (9) microbial excursions occurring in ISO-5 classified areas between May 8, 2025, and June 24, 2026. Of these, five (5) involved gloved fingertip samples, three (3) involved personnel (b) (4) samples, and one (1) involved a surface sample.

All samples yielded 1 CFU on (b) (4)), exceeding the action level of (b) (4) CFU established for ISO-5 areas. Only one excursion (No. 39, dated 2026-05-21) which involved a surface sample from location ISO-5-(b)(4) was identified as a *Bacillus Species.* No other microbial excursions from ISO 5 environment were isolated and identified.

No.	Date	Sample Type	Location	Microorganism	CFU / Media	Product
14	2025-05-08	Fingertip	ISO-5-(b) (4)	—	1 / (b) (4)	Methylprednisolone
17	2025-06-18	Fingertip	ISO 5-(b) (4)	—	1 / (b) (4)	Triamcinolone
18	2025-07-18	(b) (4)	ISO 5-(b) (4)	—	1 / (b) (4)	Triamcinolone
24	2025-09-25	Fingertip	ISO 5-(b) (4)	—	1 / (b) (4)	Triamcinolone

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32	2025-12-23	(b) (4)	ISO 5-(b) (4)	—	1 /(b) (4)	Betamethasone
33	2026-01-14	Fingertip	ISO 5-(b) (4)	—	1 /(b) (4)	Triamcinolone
35	2026-02-06	(b) (4)	ISO 5-(b) (4)	—	1 /(b) (4)	Triamcinolone
39	2026-05-21	Surface	ISO-5(b) (4)	***Bacillus Sp.***	1 /(b) (4)	Triamcinolone
40	2026-06-24	Fingertip	ISO 5(b) (4)	—	1 /(b) (4)	Triamcinolone

Gloved fingertip excursions have a zero-tolerance action level for a 503B facility, any growth after working in ISO5 areas constitutes an immediate excursion requiring investigation and corrective action. It also requires genus-level microbial identification when action levels are exceeded.

No root cause investigation, corrective action, and re-sampling results were available for the isolation of *Bacillus Species* (Excursion No. 39, 2026-05-21).

***DATES OF INSPECTION**

6/29/2026(Mon), 6/30/2026(Tue), 7/01/2026(Wed), 7/02/2026(Thu), 7/06/2026(Mon), 7/07/2026(Tue), 7/08/2026(Wed), 7/09/2026(Thu), 7/10/2026(Fri)

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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 judgment, 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."