DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Adam S Kohler, Chief Executive Officer

FIRM NAME	STREET ADDRESS
OurPharma LLC	2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, AR 72701-5013	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:

FACILITIES & EQUIPMENT

OBSERVATION 1

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

- (b)(4) Sterilization Performed in an ISO 8 Classified Room

  Batch records collected during the inspection confirm that (b)(4) sterilization was performed in Compounding Room (b)(4) which is classified as ISO 8. Specifically:

  Batch production records for two lots of Fentanyl Citrate/Bupivacaine HCl combination products, Lot 1019-01-2608-01 (Fentanyl Citrate 2mcg[base]/mL + Bupivacaine HCl 0.125% in (b)(4) added to 100mL 0.9% NaCl Bag; Master Production Batch Record No. GMP-PDTMethods-0218, Revision 01, Effective Date: July 9, 2026) and Lot 1081-01-2608-01 (Fentanyl Citrate 2mcg[base]/mL + Bupivacaine HCl 0.1% in SWFI added to 100mL 0.9% NaCl Bag; Master Production Batch Record No. GMP-PDTMethods-0239, Revision 01, Effective Date: July 15, 2026) — document that (b)(4) of the bulk drug solution was performed in an ISO 8 "(b)(4) storage room" (Compounding Room (b)(4) Specifically, in both records, Step 1.2 instructs operators to sanitize materials for transfer to this room ((b)(4) Storage room/Compounding Room (b)(4) Step 1.5 identifies (b)(4) Storage room/Compounding Room (b)(

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Beatrix D Hippe, Investigator	X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE -S Date Signed: 08-12-2026 15:31:05	8/12/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Adam S Kohler, Chief Executive Officer	
FIRM NAME OurPharma LLC	STREET ADDRESS 2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY Fayetteville, AR 72701-5013	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

as the designated area for these operations, Section 4 ((b)(4) Step 4.1 documents that (b)(4) sterilization of the bulk drug solution was performed in this room, and Step 4.4 directs removal of the (b) (4) pool bag from (b)(4) Storage/ Compounding Room (b)(4) for transfer to the cleanroom.

- No Risk Assessment or Scientific Justification Provided

You were unable to provide a risk assessment, quality risk management document, validation study, or any other documented scientific justification supporting the use of an ISO 8 classified environment for (b)(4) sterilization of sterile drug products. No documentation identified that:

☐Assessed the contamination risks associated with performing these operations outside of an ISO 5 environment;

☐Evaluated whether ISO 8 conditions are adequate to protect the sterility of the drug product solution during sterilizing (b)(4) or

☐Demonstrated that the firm identified, evaluated, and mitigated the elevated microbial and particulate contamination risk posed by the ISO 8 environment for these operations.

QUALITY

OBSERVATION 2

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically,

Annual product review (APR) records for six drug product families — Fentanyl Citrate, Fentanyl Citrate + Bupivacaine HCl, Fentanyl Citrate + Ropivacaine HCl, Hydromorphone HCl, Morphine HCl, and Ropivacaine HCl, covering review period 2024–2025 — contain multiple numerical inconsistencies,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Beatrix D Hippe, Investigator	X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE -S Date Signed: 08-12-2026 15:31:05	8/12/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026*
	FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Adam S Kohler, Chief Executive Officer	
FIRM NAME OurPharma LLC	STREET ADDRESS 2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY Fayetteville, AR 72701-5013	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

cross-product data errors, and documentation inaccuracies. When presented with these findings during the inspection, firm management confirmed that the errors were mistakes and that corrected records had not been issued prior to the inspection.

DATA INTEGRITY & STATISTICAL ERRORS

APR Document	Error Category	Finding Detail
Fentanyl Citrate + Bupivacaine HCl APR	Irreconcilable Batch Disposition Percentages	The firm reported three mutually inconsistent released percentages (97.65%, ~96.1%, and 96.5%) and could not identify which figure was correct.
Fentanyl Citrate + Bupivacaine HCl APR	Inconsistent Unit Denominator Across Reject Categories	Table 1 uses an incorrect denominator of 93,573 units — rather than the correct (b)(4) units used for all other reject categories in the same table — to calculate the in-process reject rate, a (b)(4)-unit error the firm acknowledged.
Fentanyl Citrate + Bupivacaine HCl APR	FID (b) (4) Omitted from OOS and Disposition Trend Data	FID (b) (4) was listed as a covered facility but absent from all data tables, creating a potential gap in the annual product review if production occurred. The firm confirmed the omission was accidental. Completeness of data evaluation for FID (b) (4) remains unresolved.
Fentanyl Citrate + Ropivacaine HCl APR	Mathematical Error in Visual Inspection Reject Table	Table 2 understates the "Other Major" reject rate nearly 39-fold (0.05% reported vs. ~1.95% actual), an acknowledged calculation error uncorrected at the time of inspection.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Adam S Kohler, Chief Executive Officer	
FIRM NAME OurPharma LLC	STREET ADDRESS 2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY Fayetteville, AR 72701-5013	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Hydromorphone HCl APR	Lot Count Data Copied from a Different Product Family	Table 4 of the Hydromorphone HCl APR uses Fentanyl Citrate lot counts ((b)(4)) instead of the correct Hydromorphone HCl total ((b)(4)); the firm confirmed the error but could not provide correct disposition data at the time of inspection.
Hydromorphone HCl APR	Irreconcilable Batch Disposition Percentages	Section 4 reports two irreconcilable released unit percentages — 87.4% (narrative) vs. 93.8% (Table 3) — a 6.4 percentage point discrepancy the firm confirmed but could not resolve or correct at inspection.

APR Document	Error Category	Finding Detail
Fentanyl Citrate APR	Incorrect Product Identification Header	All six pages of the Fentanyl Citrate APR carry the header "Annual Product Review: Fentanyl + Bupivacaine," which is the title of a separate APR covering a distinct product family.
Fentanyl Citrate + Bupivacaine HCl APR	Incorrect Change Control Identifier	CC-25-09-004 is referenced in the APR as covering the pool bag extension for all FIDs; the correct identifier is CC-25-09-001. The same incorrect identifier appears across all six APRs reviewed during this inspection.
Hydromorphone HCl APR & Morphine HCl APR	Identical Typographical Error in NCR Section	Both APRs contain the phrase "There was on non-conformance" in Section 8, indicating a shared template was not reviewed for accuracy prior to finalization.
Morphine HCl APR	Incorrect API Salt Form Identified	Section 1 describes compounding a "morphine citrate solution." The correct API salt form is morphine HCl. The error resulted from a copy-

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Adam S Kohler, Chief Executive Officer	
FIRM NAME OurPharma LLC	STREET ADDRESS 2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY Fayetteville, AR 72701-5013	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

		paste from another APR and was present in the finalized document.
Ropivacaine HCl APR	Incorrect Boilerplate Conclusion	The conclusions section states "No adverse quality trends, outside of the evaporation over time, were noted." The evaporation-related potency concern is specific to the Hydromorphone HCl CADD product (FID (b) (4) and does not apply to ropivacaine HCl IV bag products. Language was copied from the Hydromorphone HCl APR in error.

The volume, variety, and cross-product nature of these errors — spanning all six APRs reviewed during this inspection — indicate that the annual product review records were not adequately reviewed and verified for accuracy by the quality control unit prior to finalization. Several errors were confirmed by the firm to be the result of copy-paste from shared templates or other product family APRs, suggesting that a systematic review process was not applied prior to approval of these records.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Beatrix D Hippe, Investigator X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE -S Date Signed: 08-12-2026 15:31:05	8/12/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Adam S Kohler, Chief Executive Officer	
FIRM NAME OurPharma LLC	STREET ADDRESS 2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY Fayetteville, AR 72701-5013	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically,

Your Out of Specification (OOS) procedure, GMP-SOP-0047 (Out of Specification (OOS) SOP), does not establish defined timeframes for the completion of OOS investigations, including maximum allowable durations for Phase I laboratory investigations or Phase II full-scale investigations, nor does it define criteria or approval requirements governing the use of supplemental justifications to extend investigations beyond an initial target. During the inspection, firm management indicated that investigations typically take approximately (b)(4) days but have extended to approximately (b)(4) days, at which point a supplemental justification is added to the investigation record. Review of 13 OOS investigation records revealed that 9 required extension justifications, with open durations ranging from 35 to 205 days. The two longest investigations — OOS-25-09-004 (205 days, sterility failure, lot 1013-25-08-0005) and OOS-25-09-020 (98 days, sterility failure, lot 1013-25-09-0002) — remained open well beyond the firm's stated (b)(4)-day threshold. Because the SOP does not define completion timelines, extension criteria, or approval requirements, there is no procedural mechanism to ensure investigations are completed in a timely manner or that justifications for delays are evaluated against a consistent, established standard, creating a systemic gap in oversight that may affect the timeliness of batch disposition decisions.

OOS Number	Description	Date Initiated	Date Closed	Number of Days Open	Extension Request Approved?
OOS-24-11-001	USP 788 Method I + II failure - lot 104024110001	11/27/2024	2/18/2025	83 days	Yes
OOS-24-12-001	pH, (b) (4) stability @(b) (4), 100424060001	12/19/2024	2/20/2025	63 days	Yes
OOS-25-05-003	Low potency - lot 1028-25-04-0009 and 1028-25-05-0001	5/15/2025	6/27/2025	43 days	No

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Beatrix D Hippe, Investigator

X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE -S Date Signed: 08-12-2026 15:31:05

DATE ISSUED
8/12/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/3/2026-8/12/2026*
	FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Adam S Kohler, Chief Executive Officer

FIRM NAME	STREET ADDRESS
OurPharma LLC	2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, AR 72701-5013	Outsourcing Facility

OOS-25-05-010	Sterility failure - lot 1055-25-05-0001	5/20/2025	6/30/2025	41 days	No
OOS-25-08-013	Sterility failure - lot 1030-25-07-0005	8/27/2025	10/6/2025	40 days	Yes
OOS-25-09-004	1013-25-08-0005 sterility failure	9/8/2025	4/1/2026	205 days	Yes
OOS-25-09-020	Sterility failure - 1013-25-09-0002	9/22/2025	12/29/2025	98 days	Yes
OOS-25-10-019	Low potency - 4001-25-09-0001	10/23/2025	12/18/2025	56 days	Yes
OOS-26-03-030	1013-26-03-0001 sterility failure	3/31/2026	5/20/2026	50 days	Yes
OOS-26-06-017	stability sterility failute - 4011-25-12-0003	6/11/2026	7/16/2026	35 days	N/A
OOS-26-06-029	Low potency - 1047-01-2606-03	6/26/2026	7/31/2026	35 days	Yes

***DATES OF INSPECTION**

8/03/2026(Mon), 8/04/2026(Tue), 8/05/2026(Wed), 8/06/2026(Thu), 8/07/2026(Fri), 8/10/2026(Mon), 8/11/2026(Tue), 8/12/2026(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Beatrix D Hippe, Investigator

X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE -S Date Signed: 08-12-2026 15:31:05

DATE ISSUED

8/12/2026

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."