

## Drug Recall

**DATE OF RECALL:** October 25, 2023

**DRUG NAME:** Multiple Injection Products

**RECALLING FIRM:** Exela Pharma Sciences LLC.

**REASON FOR RECALL:** This recall was issued because particulate matter identified as silicone was observed during routine inspection of retain samples.

**FDA LINK:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-84-sodium-bicarbonate-injection-usp-50>

**OTHER DETAILS:** N/A

**RECALLED PRODUCT:**

Product Description	NDC Number	Lot Number	Expiration Date
8.4% Sodium Bicarbonate Injection, Carton, 20 Vials (Exela Label)	51754-5001-05	P0001429	11/2023
8.4% Sodium Bicarbonate Injection, Carton, 25 Vials (Exela Label)	51754-5001-04	P0001900 P0001902 P0001903 P0001909 P0001945 P0002002 P0002052	08/2024 08/2024 09/2024 09/2024 09/2024 11/2024 12/2024
8.4% Sodium Bicarbonate Injection, Single Vial (Exela Label)	51754-5001-01	P0001429 P0001902 P0001903 P0001909 P0001945 P0002002 P0002052	11/2023 08/2024 09/2024 09/2024 09/2024 11/2024 12/2024
8.4% Sodium Bicarbonate Injection, Carton, 20 Vials (Civica Label)	72572-0740-20	P0001912	08/2024

8.4% Sodium Bicarbonate Injection, Single Vial (Civica Label)	72572-0740-01	P0001912	08/2024
Midazolam in 0.8% Sodium Chloride Injection, 100 mg/100 mL, Carton, 25 Vials	51754-2131-04	10001088	07/2024
Midazolam in 0.8% Sodium Chloride Injection, 100 mg/100 mL, Single Vial	51754-2131-01	10001088	07/2024
ELCYS (cysteine hydrochloride Injection), 500 mg/10 mL, Carton	51754-1007-03	10000798	03/2025
ELCYS (cysteine hydrochloride Injection), 500 mg/10 mL, Single Vial	51754-1007-01	10000798	03/2025

