

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies

Exela Pharma Sciences LLC is recalling 49 lots of 8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 ml vial. The affected lots are packaged only in 20 count cartons. This recall is being made to the Dispensing Level.

This recall is being carried out in an abundance of caution due to a potential safety concern with vial breakage while preparing the product for administration. The standard process of solution extraction via a syringe does not require pressurizing the vial but in some instances, the health care provider may apply pressure to the vial that can on occasion result in vial breakage. There have been no reports of sterility failure.

The affected lots (listed below) were distributed between: 12/16/2021 - 08/10/2022.

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001370	10/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001371	09/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001372	10/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001433	11/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001434	11/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001443	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001468	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001469	12/2023

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001470	12/2023

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001495	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001505	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001506	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001509	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001510	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001511	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001512	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001560	01/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001561	01/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001562	01/2024

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001564	01/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001566	01/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001567	01/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001568	01/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001571	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001572	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001573	02/2024

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001574	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001578	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001579	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001580	02/2024

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001583	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001586	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001587	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001588	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001593	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001594	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001610	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001618	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001619	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001644	03/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001645	03/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001646	03/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001654	03/2024

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001662	03/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001664	03/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 51754-5001-5 Inner Vial: 51754-5001-1	P0001730	05/2024

Batches Manufactured by Exela Pharma Sciences LLC for Civica Inc.

Lots packaged under a Civica Inc. label.

Item Description	NDC	Lot	Expire Date
8.4% Sodium Bicarbonate Injection, USP	Carton: 72572-740-20 Inner Vial: 72572-740-1	P0001497	12/2023
8.4% Sodium Bicarbonate Injection, USP	Carton: 72572-740-20 Inner Vial: 72572-740-1	P0001600	02/2024
8.4% Sodium Bicarbonate Injection, USP	Carton: 72572-740-20 Inner Vial: 72572-740-1	P0001663	03/2024