

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 and procedures to determine if any corrective action is required.

This is to inform you that Astral SteriTech Pvt. Ltd. (Astral) is initiating a recall of all products manufactured at its facility in Vadodara, Gujarat, India that are still within expiry as of the date of this letter. These affected products are sterile antibiotic powders for injection that were manufactured between May 2020 and April 2023. These products were distributed by and labeled in the names of the following distribution partners: Civica, Inc., Meitheal Pharmaceuticals, Piramal Critical Care, or Xellia Pharmaceuticals. Please refer to the table for a complete list of affected products, including NDC numbers. The recall is being initiated due to quality concerns Astral identified while investigating out-of-specification results in environmental monitoring at its manufacturing facility. Because of these concerns, the sterility of products manufactured at Astral’s facility cannot be assured. To date, Astral has not received reports of adverse events relating to this issue. Intravenous or intramuscular administration of a product for which sterility cannot be assured could result in serious systemic infections. Further distribution or use of these products should cease immediately.

Product Description	Distributor Name on Label	Strength	NDC Number
Ampicillin Sodium USP (sterile)	Piramal Critical Care	250mg	66794-220-41
	Piramal Critical Care	500mg	66794-221-41
	Piramal Critical Care	1g	66794-222-41
	Piramal Critical Care	2g	66794-223-41
	Piramal Critical Care	10g	66794-224-15
	Xellia Pharmaceuticals	250mg	70594-084-02
	Xellia Pharmaceuticals	500mg	70594-085-02
	Xellia Pharmaceuticals	1g	70594-086-02
	Xellia Pharmaceuticals	2g	70594-087-02
	Xellia Pharmaceuticals	10g	70594-088-01
	Civica, Inc.	1.5g	72572-021-10
	Civica, Inc.	3g	72572-022-10
	Meitheal Pharmaceuticals	1.5g	71288-005-20
	Meitheal Pharmaceuticals	3g	71288-006-30
	Meitheal Pharmaceuticals	15g	71288-007-75
Ampicillin & Sulbactam For Injection USP (Sterile Mixture 2:1)	Piramal Critical Care	1.5g	66794-206-41
	Piramal Critical Care	1.5g	66794-241-41
	Piramal Critical Care	3g	66794-207-41
	Piramal Critical Care	3g	66794-242-41
	Piramal Critical Care	15g	66794-208-15
	Piramal Critical Care	15g	66794-243-15
	Xellia Pharmaceuticals	1.5g	70594-081-02
	Xellia Pharmaceuticals	3g	70594-082-02
	Xellia Pharmaceuticals	15g	70594-083-01

	Civica, Inc.	1g	72572-057-10
	Civica, Inc.	2g	72572-058-10
Cefepime for Injection (Mixture of Cefepime HCl and L-arginine) Sterile	Meitheal Pharmaceuticals	2g	71288-009-20
	Piramal Critical Care	1g	66794-209-41
	Piramal Critical Care	2g	66794-210-41
	Xellia Pharmaceuticals	1g	70594-089-02
	Xellia Pharmaceuticals	2g	70594-090-02
	Piramal Critical Care	250mg	66794-211-42
	Piramal Critical Care	500mg	66794-212-42
	Piramal Critical Care	1g	66794-213-42
	Piramal Critical Care	2g	66794-214-42
	Piramal Critical Care	10g	66794-215-15
Ceftriaxone Sodium Sterile	Xellia Pharmaceuticals	250mg	70594-094-02
	Xellia Pharmaceuticals	500mg	70594-095-02
	Xellia Pharmaceuticals	1g	70594-096-02
	Xellia Pharmaceuticals	2g	70594-097-02
	Xellia Pharmaceuticals	10g	70594-098-01
	Civica, Inc.	3.375g	72572-576-10
	Civica, Inc.	4.5g	72572-577-10
	Meitheal Pharmaceuticals	2.25g	71288-002-31
	Meitheal Pharmaceuticals	3.375g	71288-003-31
	Meitheal Pharmaceuticals	4.5g	71288-004-51
Piperacillin Sodium + Tazobactam Sodium (8:1) Sterile	Piramal Critical Care	2.25g	66794-216-41
	Piramal Critical Care	3.375g	66794-217-41
	Piramal Critical Care	4.5g	66794-218-41
	Xellia Pharmaceuticals	2.25g	70594-078-02
	Xellia Pharmaceuticals	3.375g	70594-079-02
	Xellia Pharmaceuticals	4.5g	70594-080-02