

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.

Sun Pharma is recalling the following lot of Testosterone Cypionate Injection, USP:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Testosterone Cypionate Injection, USP, 200mg/ml	Carton containing single 1 ml Vial	HAC1974A	62756-015-40	6/2023
		HAC1978A	62756-015-40	6/2023

This product recall has been initiated in response to an investigation for an out-of-specification (OOS) and out-of-trend (OOT) impurity result for two batch s of Testosterone Cypionate Injection, USP, which were not released to the market. The cause of the OOS and OOT in impurity was found to be the active pharmaceutical ingredient (APT) lot which was also used to manufacture distributed lots HAC197A and HAC1978A. However, no OOS or OOT was reported for either of the distributed lots.

Sun Pharma conducted a health hazard evaluation (HHE), and found that while there are no out of specification results for lots HAC1974A and HAC1978A, the impurity level may increase throughout the shelf life of the product. Therefore, impact on patient safety cannot be completely ruled out in the long term. Out of an abundance of caution, Sun Pharma has decided to recall the aforementioned lots.

Sun Pharmaceutical Industries Inc. initiated shipment of this product September 23rd, 2021.