

The Board of Pharmacy has received notice of the following product recall:

Piramal Critical Care Inc. is recalling Gablofen (Baclofen Injection) 50 mcg/ml pre-filled syringe packaged lots 2155-111 and 2155-111A. Both lots are packaged with NOC code 66794-151-01.

This recall has been initiated as a precaution due to the presence of an unknown impurity observed during shelf life of the product. The investigation to date indicates that the unknown signal is a leachable from the primary packaging and is below safety and toxicological thresholds, hence is unlikely to cause any patient safety impact. To date, Piramal Critical Care has not received any Adverse Event Reports related to the lot in question. Pending confirmatory testing, Piramal Critical Care is initiating this recall out of an abundance of caution.

This product began shipping on 27 October 2017. This recall is to retail/pharmacy level.

The Board of Pharmacy strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.