

*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.*

**Esomeprazole Magnesium Delayed-Release Capsules USP, 20mg & 40mg**

This notice is to inform you of a product recall involving:

<b>Product Name</b>	<b>Package Description</b>	<b>Lot Number</b>	<b>NDC Number</b>	<b>Expiration Date</b>
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg	90 Count	AC14299	63304-734-90	12/2022
Esomeprazole Magnesium Delayed-Release Capsules, USP40mg	90 Count	AC14304	63304-735-90	12/2022

This recall has been initiated in response to an out of specification assay test result, which was observed during routine stability testing on lot AC14299. The assay result is 112.6%, slightly higher than the upper specification limit of 110.0%. An investigation was conducted by Sun Pharma and found that lot AC14304 may also be impacted, although no out of specification result has so far been observed.

Sun Pharma conducted a Health Hazard Evaluation (HHE) and found that the out of specification assay result is unlikely to pose any risk to patient safety. However, out of an abundance of caution, Sun Pharma has decided to voluntarily recall the aforementioned lots.

Sun Pharmaceutical Industries Inc. initiated shipment of this product on 03/05/2021.