

*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 Pharmaceutical Industries, Inc would like to inform you of a product recall involving Clindamycin Phosphate Topical Solution USP, 1%.

This recall has been initiated in response to Out of Specification (OOS) results observed in specific related compounds test for Clindamycin Phosphate Topical Solution USP, 1%, Batch AD13345, during analysis at the 24 month long term stability station, at expiry (25°C, 60%RH). The three (3) listed batches, manufactured as part of the same campaign are impacted and, therefore, subject to this recall. OOS in Total Impurities was observed for lots AD30154 & AD31143 and OOS in Assay was observed for lot AD31143.

Based on the Health Hazard Evaluation, *“The presence of this impurity raises the possibility of local adverse events and flare-ups of acne due to reduced efficacy. Therefore, a minor risk to the patient cannot be ruled out. Overall, the elevated impurity level of Clindamycin 2-Phosphate Sulfoxide and the reduced assay value in Clindamycin Phosphate Topical Solution 1% (Batch AD31143), may pose a minor risk to patients compared to the known safety profile of the drug.”*

All lots complied with all of the established product specifications at the time the products were released for distribution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product between January 1, 2024, and April 16, 2024.

<b>Product Name</b>	<b>Package Description</b>	<b>NDC#</b>	<b>Lot#</b>	<b>Expiration Date</b>
Clindamycin Phosphate Topical Solution USP, 1%	60 ml bottle	51672-4081-4	AD30154	11/30/2025
Clindamycin Phosphate Topical Solution USP, 1%	60 ml bottle	51672-4081-4	AD31143	11/30/2025
Clindamycin Phosphate Topical Solution USP, 1%	60 ml bottle	51672-4081-4	AD31145	11/30/2025