

*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 notify you that Viona Pharmaceuticals Inc. (“Viona”), is withdrawing drug product mentioned in the table below at the **RETAIL LEVEL**.

An out of trend (OOT) result reported in Related Substance test for “Any Unspecified Degradation Product (unknown impurity)” in Clindamycin Phosphate Gel USP 1%, batch number T401056 during the finished product testing for batch release; 'Any unspecified degradation product' found 0.34% (was eluting at RRT 1.49) against the limit of Not More Than 0.5%.

Investigation reveals that the observed OOT results in Related Substance for 'any unspecified degradation product' is attributed to the varnish used in the specific lot of primary packing material i.e. Laminated Tube used for filling the drug product.

As a precautionary measure, Viona initiating withdrawal for below mentioned 3 batches which were packed using the impacted lot of Laminated tubes.

<b>S. No</b>	<b>Product Detail</b>	<b>NDC Number</b>	<b>Lot Number</b>	<b>Expiry Date</b>	<b>Count</b>	<b>Distribution Start Date</b>	<b>Distribution End Date</b>
1.	Clindamycin Phosphate Gel, USP 1%	72578-118-01	T400637	03/2026	30 G Laminated Tube	10/11/2024	11/13/2024
2.	Clindamycin Phosphate Gel, USP 1%	72578-118-01	T400638	03/2026	30 G Laminated Tube	10/25/2024	12/02/2024

3.	Clindamycin Phosphate Gel, USP 72578-118-01 1%	T400639	03/2026	30 G Laminated Tube	12/02/2024	01/17/2025
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