URGENT: DRUG RECALL WHOLESALER NOTIFICATION

June 12, 2023

Dear Wholesaler,

The purpose of this letter is to advise you that Amring Pharmaceuticals (Amring) is voluntarily recalling two (2) lots of Tranexamic Acid, USP Tablets to the Wholesaler level due to an Out of Specification (OOS) result for the conductivity of one of its excipients, USP Purified Water. **Tranexamic Acid** is manufactured for Amring by Mikart, LLC.

Our records indicate that you may have received shipments of the impacted Tranexamic Acid, USP tablet lots distributed between January 31, 2023-March 06, 2023. Therefore, please examine your inventory immediately to determine if you have any quantities of the affected product lots remaining in stock.

Amring has informed the U.S. Food and Drug Administration of this voluntary recall.

PRODUCT INFORMATION

Tranexamic Acid, USP Tablets

Lot#	NDC#	Expiry Date	UPC Code	Date(s) Distributed
X220317A	69918-301-30	09/2025	369918301303	January 31, 2023-February 14, 2023
X220318A	69918-301-30	09/2025	369918301303	February 14, 2023-March 06, 2023

Level:	Class III, Wholesale/Distributor Level
Reason:	Tranexamic Acid Tablets, USP Lots X220317A and X220318A were manufactured using excipients Purified Water, USP that did not meet the filed specification for Conductivity. Purified water is used in wet granulation and equipment rinsing.
Health Hazard Assessment:	There are no adverse health consequences expected as a result of this issue.

ACTIONS REQUIRED

Upon receipt of this letter, please take the following actions:

1. If you have inventory of the recalled product lots, immediately quarantine, stop distributing, dispensing and/or using any of affected lots above.

2. Conduct a physical count of the affected product lots in your possession and record this information on the Business Reply Form included with this letter.

3. Please further distribute this recall letter to your consignees and request a response using the Business Reply Form, if applicable.

4. Promptly complete the attached **Business Reply Form** and reply via fax 877-884-7828 or by email at amring4976@sedgwick.com, even if you have no product to return.

5. When returning the recalled product, attach the prepaid UPS Authorized Return shipping label to the outside of the return carton. Return the recalled product and completed recall stock response form to:

   Sedgwick
   Event 4976
   2670 Executive Drive, Suite A
   Indianapolis, IN, 46241, U.S.A.

6. If you have no recall product to return, please complete the **Business Reply Form** and return via email within five (5) business days of receipt to ensure we account for all recalled units.

7. Please **DO NOT** return any products that are not the subject of this recall. Also, do not include non-Amring or any other Amring labeled not subject to this Recall in your shipment.

CONTACT INFORMATION

Product Returns:
Sedgwick
Event 4976
2670 Executive Drive, Suite A
Indianapolis, IN, 46241, U.S.A.
1-888-266-7923
8:00am – 5:00pm EST

Adverse Events/Product Complaints/Medical Information:
Amring Pharmaceuticals at:
1-844-267-4641 Option 1
9:00 am – 5:00pm EST
For after-hours assistance, please leave a voicemail with contact information. A response will be provided within 48 business hours.

FDA contact information for reporting adverse events: Online at www.fda.gov/medwatch/report.htm or call FDA 1-800-FDA-1088.

We appreciate your immediate attention and cooperation, and we sincerely regret any inconvenience caused by this recall. At Amring, our priority is commitment to providing safe and effective products to our customers and patients.

Thank you for your assistance in this matter.

Sincerely,
Amring Pharmaceuticals, Inc.