Eugia US LLC (f/k/a Auro Medics Pharma LLC) Issues Voluntary Nationwide Recall of Vancomycin Hydrochloride for Injection USP 1.25g/Vial-30mL (Single Dose Vial) Due to Presence of Particulate Matter

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FOR IMMEDIATE RELEASE –November 06,2026 – East Windsor, New Jersey, Eugia US LLC (f/k/a Auro Medics Pharma LLC) is voluntarily recalling lot number 3VM26026A of Vancomycin Hydrochloride for Injection USP 1.25g/Vial-30mL (Single Dose Vial) to the hospital/healthcare facility/user level due to the presence of particulate matter identified as a glass particle inside the vial.

Risk Statement: There is a reasonable probability that use of product containing glass particulates can cause serious adverse health consequences such as blockage and clotting in blood vessels, which can cut off blood flow to vital organs, lead to a life-threatening blood clot in the lungs (pulmonary embolism) and cause permanent organ damage or death. Additionally, these particles may cause local vein irritation, inflammatory reaction, aggravation of preexisting infections, and allergic reactions. Greater susceptibility may exist in neonates, infants and patients with compromised organ function. To date, Eugia US LLC has not received any reports of adverse events related to this recall.

Vancomycin hydrochloride for injection is a glycopeptide antibacterial indicated in adult and pediatric patients (Neonates and Older) for the treatment of Septicaemia, Infective Endocarditis, Skin and Skin Structure Infections, Bone Infections and Lower Respiratory Tract Infections.

The recalled product is packaged in 30 mL vial and packed as 10 (vials) X 10 (Printed cartons) X 01 (Shipper) with NDC code as 55150-471-01.

The product can be identified by product name on carton (NDC 55150-471-10) and vial (NDC 55150-471-01) label and with lot number 3VM26026A and Exp. JUL 2028

Eugia US LLC shipped the entire lot to wholesalers nationwide from September 2, 2026, through September 15, 2026.

The Company is notifying its distributors and customers by recall letters and is arranging for return/replacement of all recalled products. Wholesalers/hospitals/pharmacies, institutions, and doctors with existing inventory of the recalled product lot should discontinue use and quarantine the product immediately. If you have further distributed the recalled product lot, please notify your accounts and or any additional locations which may have received the recalled product. Hospitals and institutions should inform Healthcare professionals in your organization of this recall.

Consumers with medical questions regarding this recall or reporting an adverse event can contact Eugia US LLC from 8:00 am to 5:00 p.m. (EST) Monday to Friday at:

- 1-866-850-2876 Option 2
- pvg@aurobindousa.com

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
If you have any general questions regarding the return of this product, please contact Qualanex at 1-800-505-9291 or email recall@qualanex.com (live calls received 7:00 am to 4:00 pm M-F CST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm

- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

The Product label is as shown below:

