

IMPACT ANALYSIS: EMCURE PHARMA, SANAND

cGMP Inspection Raises Regulatory Focus










20th MAY 2026



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Emcure Pharma Receives 7 Form 483 Observations at Sanand Facility: cGMP Inspection Raises Regulatory Focus

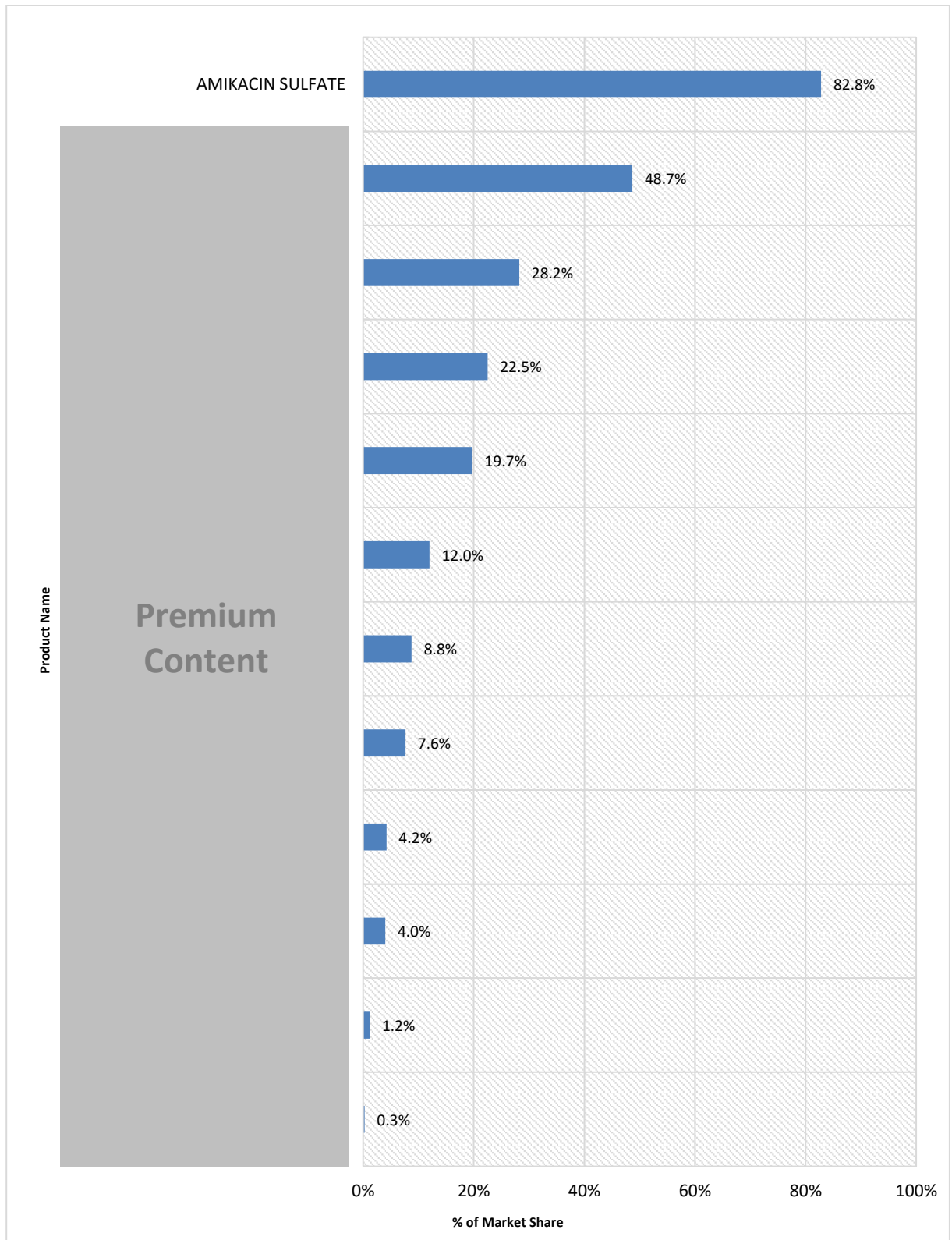
Emcure Pharmaceuticals' formulations manufacturing facility located at G.I.D.C., Taluka-Sanand, Ahmedabad, Gujarat, underwent a U.S. FDA cGMP inspection from May 6, 2026 to May 15, 2026, which concluded with the issuance of 7 Form 483 observations.

- **Facility Profile:** The facility manufactures  **generic** and  **authorized generic** injectable product for the U.S. market including injectables, intravenous solutions, liposomal injectables, and specialty sterile formulations.
- **Top Generic Products Manufactured (By Sales):**  
- **Products Likely Exposed to Shortages** (Based on Market Share >20%, Sales >\$3Mn & No Backup Manufacturing): No products identified under shortage-risk criteria.
- **Revenue Contribution:** The facility contributes ~  **Mn** in annual U.S. ANDA/NDA sales, accounting for  % of total estimated U.S. sales (excluding Biosimilar Sales). **Authorized generic**  is already genericized with multiple competitors, resulting in limited market exclusivity.
- **Backup Coverage:** Approximately  of facility-linked U.S. sales are supported through alternate manufacturing sites, while  sales remain without backup manufacturing coverage.
- **Financial Impact:** Prolonged remediation timelines could increase compliance costs and impact injectable product supply without backup facility.
- **Inspection History:** The facility maintained a VAI compliance history across the last three U.S. FDA inspections (Mar 2020, Feb 2023, and Apr 2024).

The Form 483 observations indicate potential compliance concerns related to manufacturing practices or quality systems; however, the company has committed to addressing all observations within the stipulated timeline.

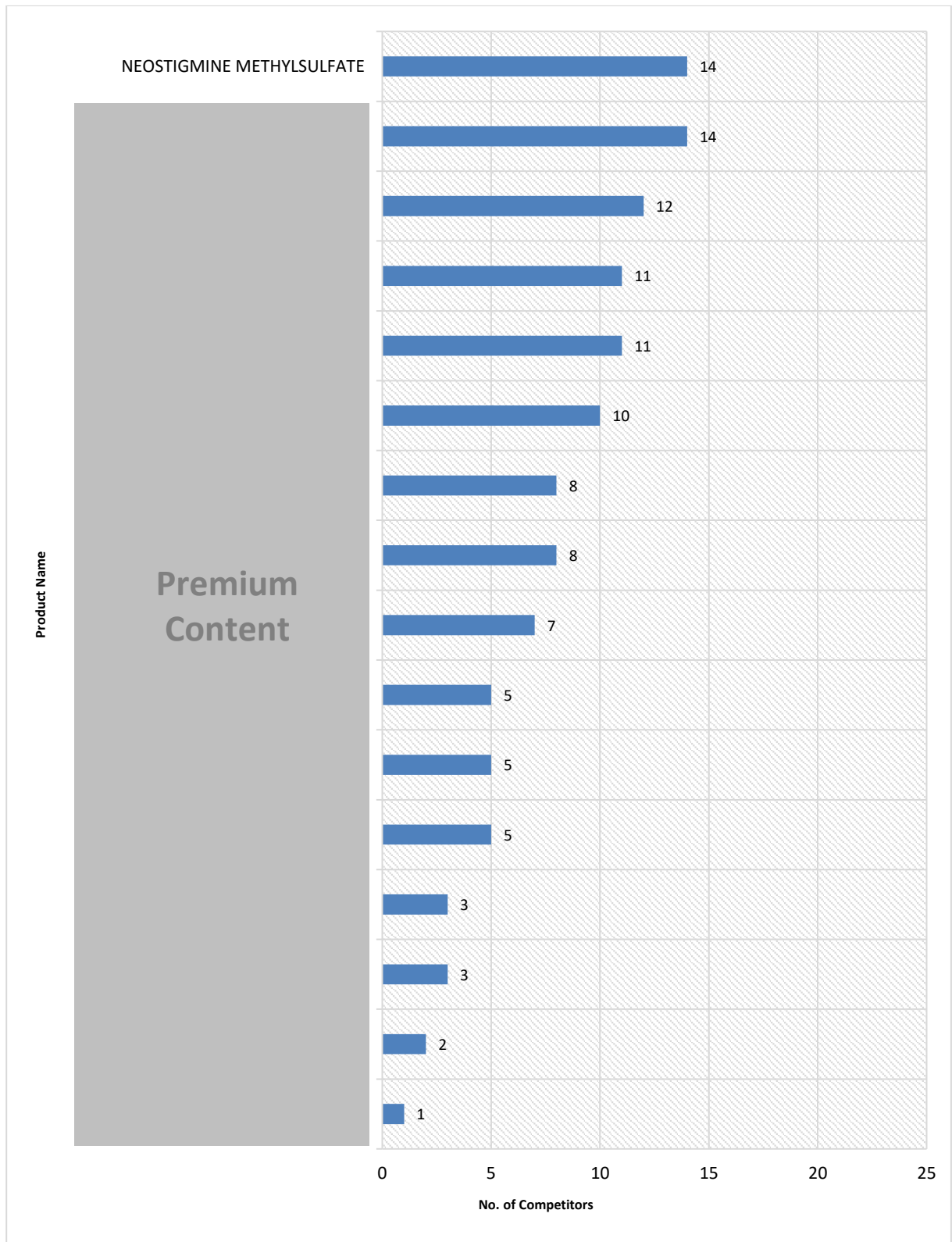
Source: GenUS, Research Delta Advisors, *Sales (IN USD MN): Last Year Sales as per Medicaid Drug Rebate Program (Q1-Q4 FY2025)

CHART 1: EMCURE PRODUCT WISE MARKET SHARE



Note: Market share calculated based on 12 months sale ended in Q4-2025.

CHART 2: GENERIC COMPETITION



Note: Number of competitors counted as of today in same RLD

Detailed Analyses



Impact Analysis: Emcure Pharma, Sanand



TABLE 1: PRODUCTS

Sr. No.	ApplNo	Generic Name	Brand Name	Dosage; Form	ANDA Owner	Other Gx competi-tors	Other Facility for same ANDA	Complexity	Sales* (IN USD MN)	% of US Sales*	Market Share	
1	206408	PROPOFOL	DIPRIVAN	INJECTABLE; INJECTION	AVESTA PHARMA	8	-	-	4.53	9.8%	4.0%	
2	<p>Premium Content</p>											
3												
4												
5												
6												
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Source: GenUS, Research Delta Advisors, *Market share based on total revenue of therapeutically equivalent NDA and ANDAs, *17422 is NDA Auth Generic *Sales (IN USD MN): Sales as per Medicaid Drug Rebate Program (Q1-Q4 FY2025). Total Emcure Pharma US Sales for ANDA/NDA is [redacted] Mn



TABLE 2: INSPECTION HISTORY

Inspection End Date	Classification
04/05/2024	Voluntary Action Indicated (VAI)
02/16/2023	Voluntary Action Indicated (VAI)
03/17/2020	Voluntary Action Indicated (VAI)

-----End of the Report-----

