

IMPACT ANALYSIS: ALKEM LABS, DAMAN

Regulatory Scrutiny at Major U.S. Manufacturing Site

7th MAY 2026



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Alkem Laboratories Received 7 Form 483 Observations at Daman Facility: Regulatory Scrutiny at Major U.S. Manufacturing Site

Alkem Laboratories' manufacturing facility located at Amaliya, Daman, India, underwent a U.S. FDA inspection from April 20, 2026 to May 1, 2026 concluded with the issuance of 7 form 483 observations. The inspected site is one of Alkem's largest U.S.-focused manufacturing facilities and plays a critical role in supplying multiple high-volume generic products to the U.S. market.

- **Facility Profile:** The Amaliya, Daman facility manufactures **68 generic** products for the U.S. market, including tablets, capsules, oral suspensions, solutions, ER/DR formulations, syrups, granules, and nasal sprays.
- **Top Generic Products Manufactured:** [REDACTED] [REDACTED] [REDACTED] [REDACTED]
- **Products Likely Exposed to Shortages** (Based on Market Share >20%, Sales >\$3Mn & No Backup Manufacturing): [REDACTED]
- **Revenue Contribution:** The Daman facility contributes [REDACTED] Mn in annual U.S. generic sales, accounting for [REDACTED] % of Alkem Laboratories' total estimated U.S. generic revenue of [REDACTED] Mn, indicating very high operational dependence on the site.
- **Backup Coverage:** Approximately [REDACTED] of facility-linked U.S. sales are supported through alternate manufacturing sites, while nearly [REDACTED] remain without backup manufacturing coverage, creating elevated supply-chain and business continuity risk if regulatory escalation occurs.
- **Financial Impact:** Due to the facility's high contribution to Alkem's U.S. generics business and significant non-backed-up product exposure, prolonged remediation timelines or regulatory escalation could affect future ANDA approvals, increase compliance-related expenses, and create supply risk for high market share products.
- **Inspection History:** The facility showed improved compliance after a 2018 VAI classification, with subsequent NAI outcomes. However, the latest Form 483 indicates renewed FDA scrutiny at the site.

The Form 483 observations indicate potential compliance concerns related to manufacturing practices, quality systems, or product safety; however, the company has committed to addressing

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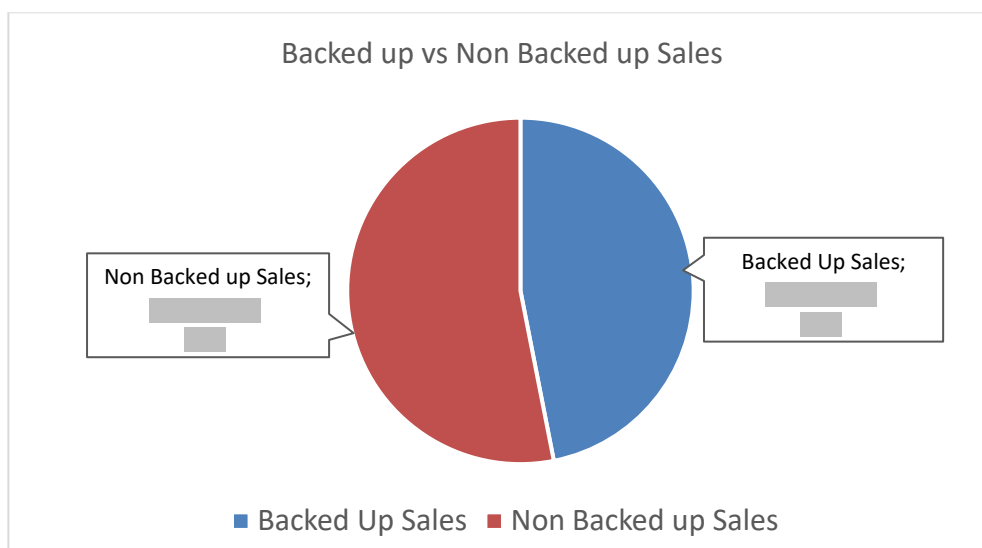


all observations within the stipulated timeline. While no major enforcement action has been initiated, timely remediation will be important to avoid potential impact on current supply and future approvals. The recent EU GMP certification from the Malta Medicines Authority also suggests that the facility maintains acceptable compliance standards under European regulations.

TABLE 1: PRODUCT LIKELY EXPOSED TO SHORTAGES

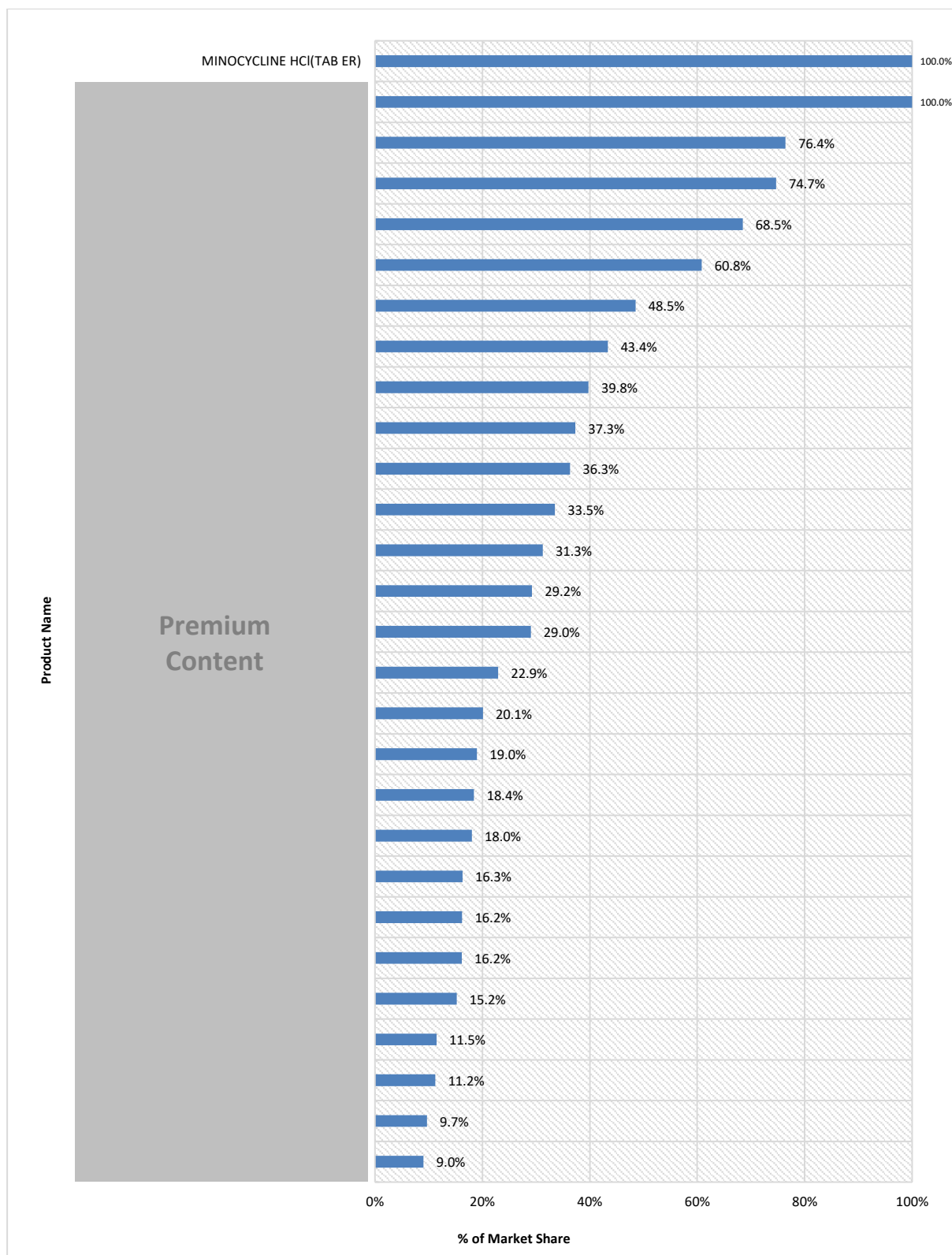
Sr. No.	ApplNo	Generic Name	Brand Name	Dosage; Form	ANDA Owner	Other Gx competi-tors	Other Facility for same ANDA	Complexity	Sales* (IN USD MN)	% of US Sales*	Market Share
1	Premium Content										
2											
3											
4											
5	210568	CEFPODOXIME PROXETIL	VANTIN	TABLET; ORAL	ALKEM	3	-	Naturally sourced ingredients	3.16	0.9%	36.3%

CHART 1: PRODUCT SALES



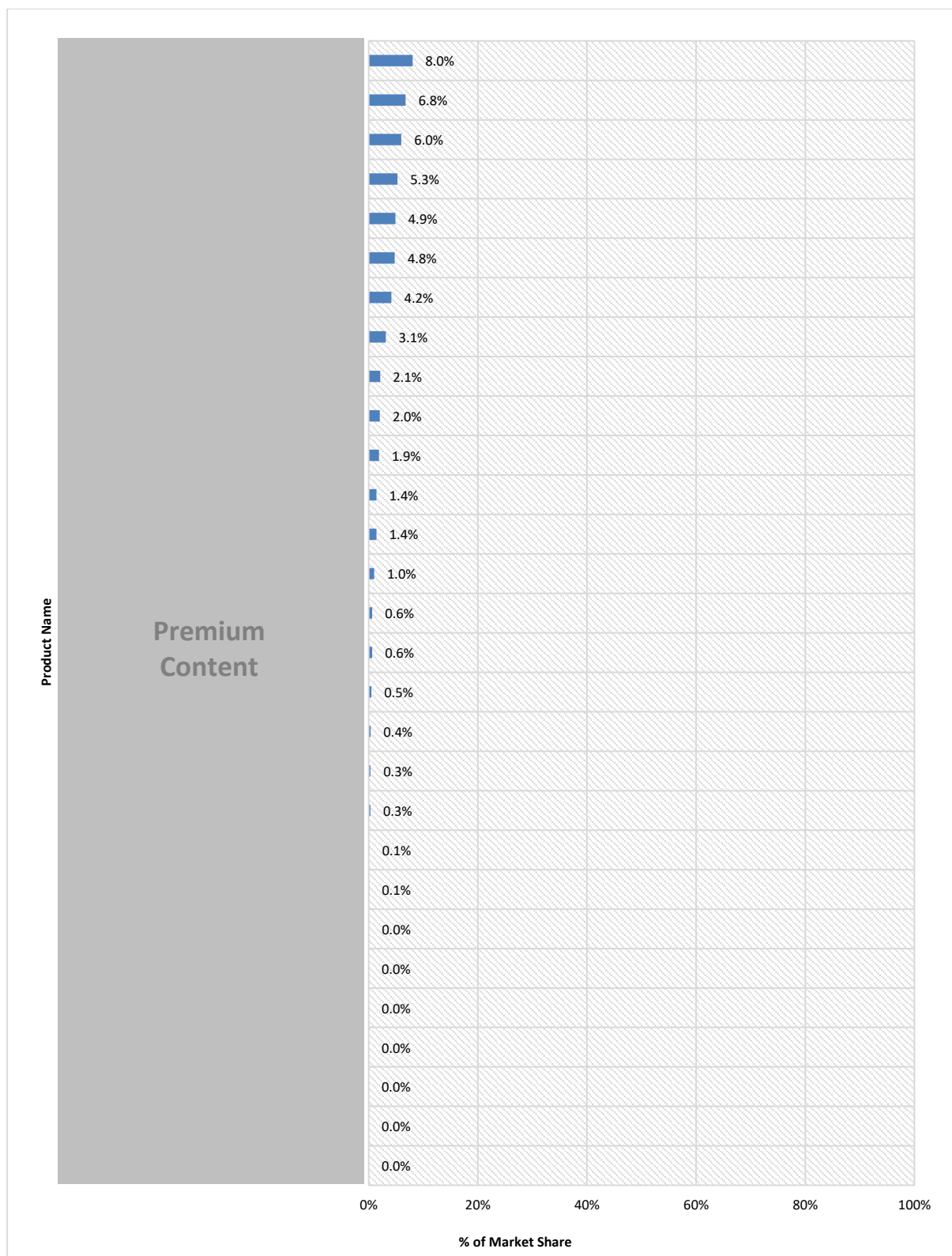
Source: GenUS, Research Delta Advisors, *Market share based on total revenue of therapeutically equivalent NDA and ANDAs, *Sales (IN USD MN): Last Year Sales as per Medicaid Drug Rebate Program (Q1-Q4 FY2025)

CHART 2: ALKEM PRODUCT WISE MARKET SHARE



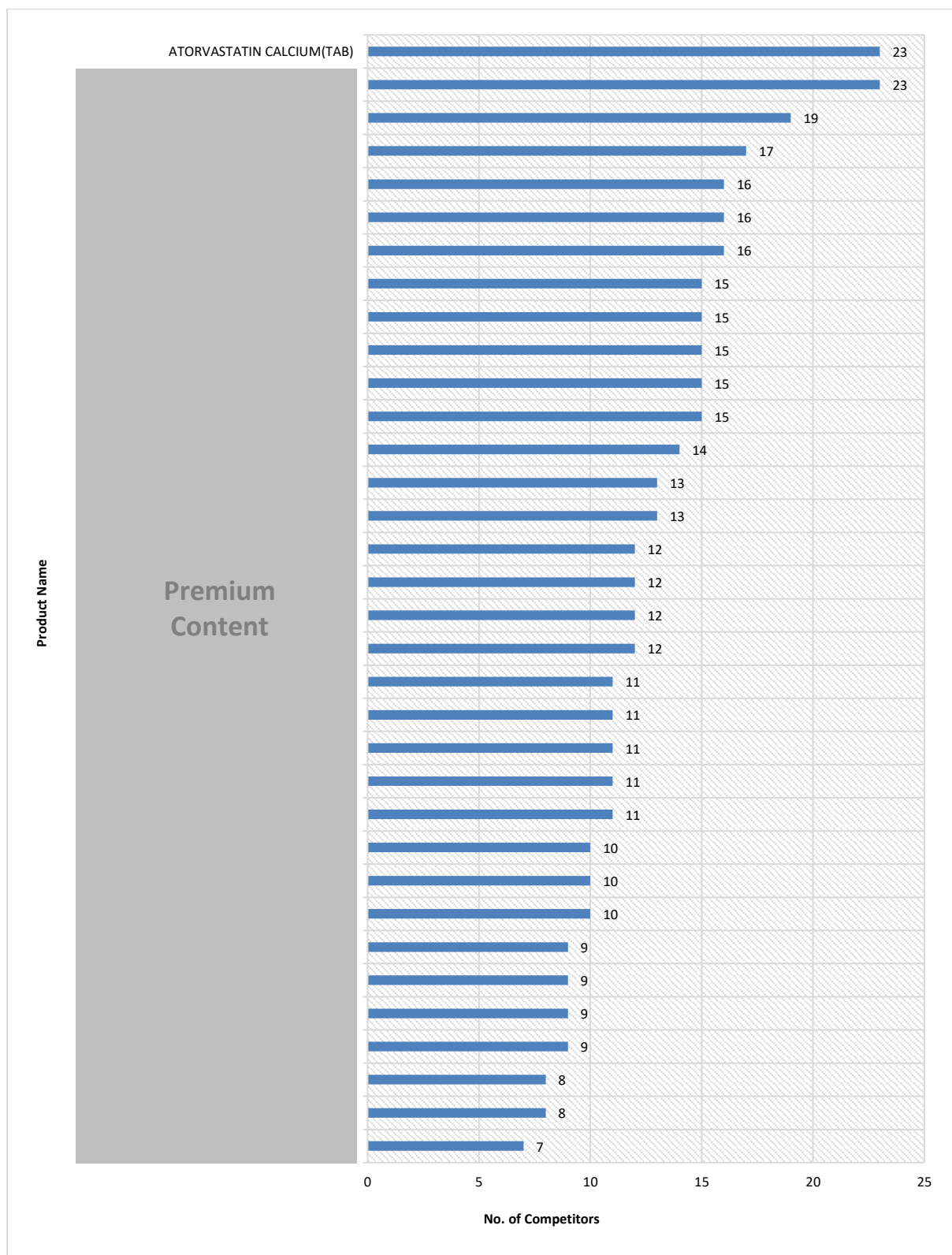
Note: Market share calculated based on 12 months sale ended in Q4-2025. In some products brand name given in bracket to differentiates multiple products with same generic name but different RLD. TAB= Tablet, CAP= Capsule, SUS= Suspension, SOL= Solution, GRA= Granules, ER/DR= Extended/Delayed Release.

CHART 2: ALKEM PRODUCT WISE MARKET SHARE(Continued)



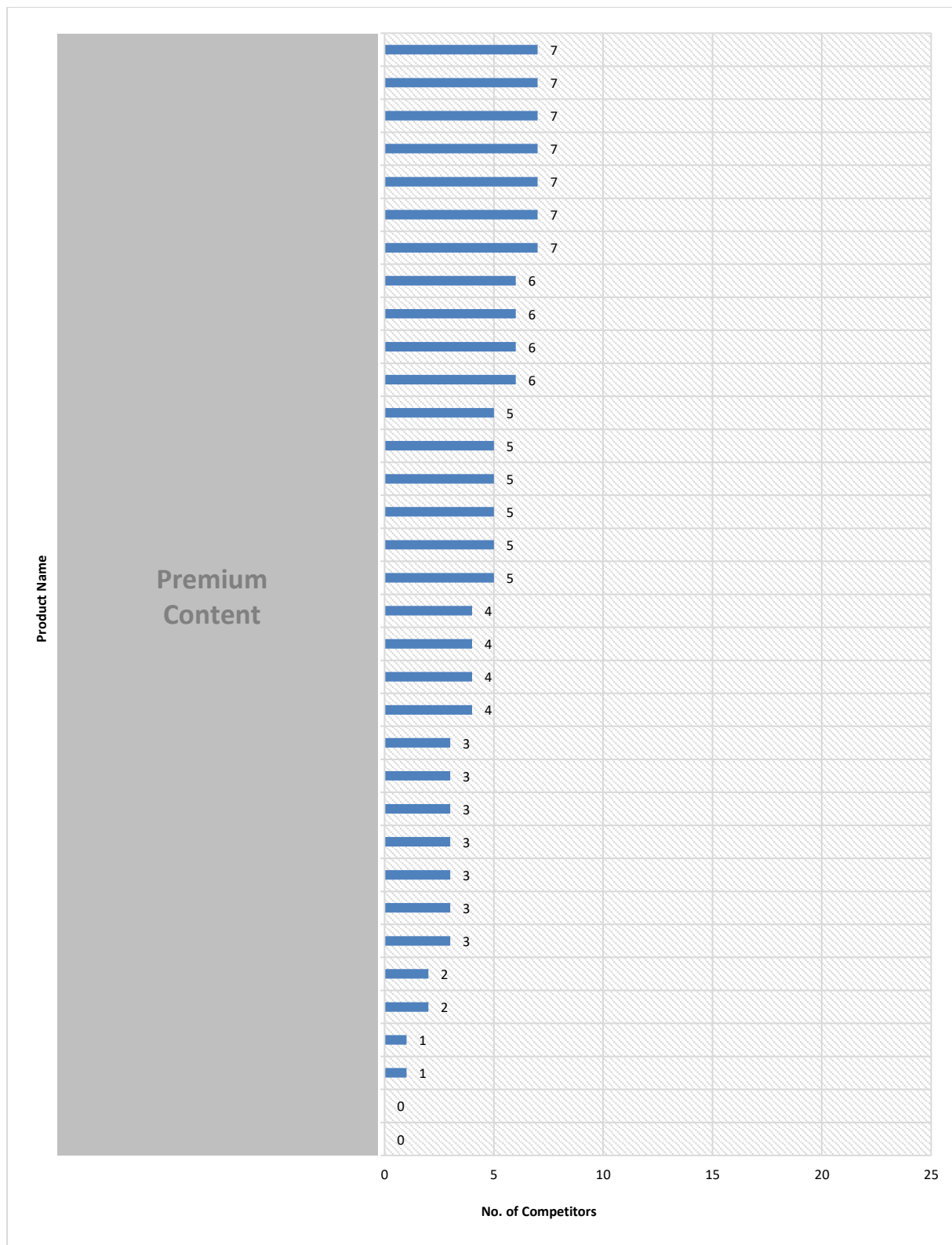
Note: Market share calculated based on 12 months sale ended in Q4-2025. In some products brand name given in bracket to differentiates multiple products with same generic name but different RLD. TAB= Tablet, CAP= Capsule, SUS= Suspension, SOL= Solution, GRA= Granules, ER/DR= Extended/Delayed Release.

CHART 3: GENERIC COMPETITION



Note: Number of competitors counted as of today in same RLD. In some products brand name given in bracket to differentiates multiple products with same generic name but different RLD. TAB= Tablet, CAP= Capsule, SUS= Suspension, SOL= Solution, GRA= Granules, ER/DR= Extended/Delayed Release.

CHART 3: GENERIC COMPETITION(Continued)



Note: Number of competitors counted as of today in same RLD. In some products brand name given in bracket to differentiates multiple products with same generic name but different RLD. TAB= Tablet, CAP= Capsule, SUS= Suspension, SOL= Solution, GRA= Granules, ER/DR= Extended/Delayed Release.

Detailed Analyses



**TABLE 2: GENERIC 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	78925	AMLODIPINE BESYLATE	NORVASC	TABLET; ORAL	ALKEM	19	1) ALKEM, BADDI(HP), IND 2) VKT PHARMA, SRIKAKULAM(AP), IND	-	45.73	13.6%	33.5%
2	Premium Content										
3											
4											
5											
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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
22											
23											
24											
25											
26											
27											
28											
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44											

Premium
Content

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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
45	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
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Premium Content

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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
67	Premium Content										
68											
Total											

Source: GenUS, Research Delta Advisors, *Market share based on total revenue of therapeutically equivalent NDA and ANDAs

*Sales (IN USD MN): Sales as per Medicaid Drug Rebate Program (Q1-Q4 FY2025). Total Alkem Labs' US Sales for ANDA/NDA is ~\$ Mn

TABLE 3: INSPECTION HISTORY

Inspection End Date	Classification
08/30/2019	No Action Indicated (NAI)
01/18/2019	No Action Indicated (NAI)
03/27/2018	Voluntary Action Indicated (VAI)

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