

IMPACT ANALYSIS: BIOCON, BIOCON PARK, BENGALURU

Moderate Risk to Approvals & Limited Generic Exposure

5th MAY 2026



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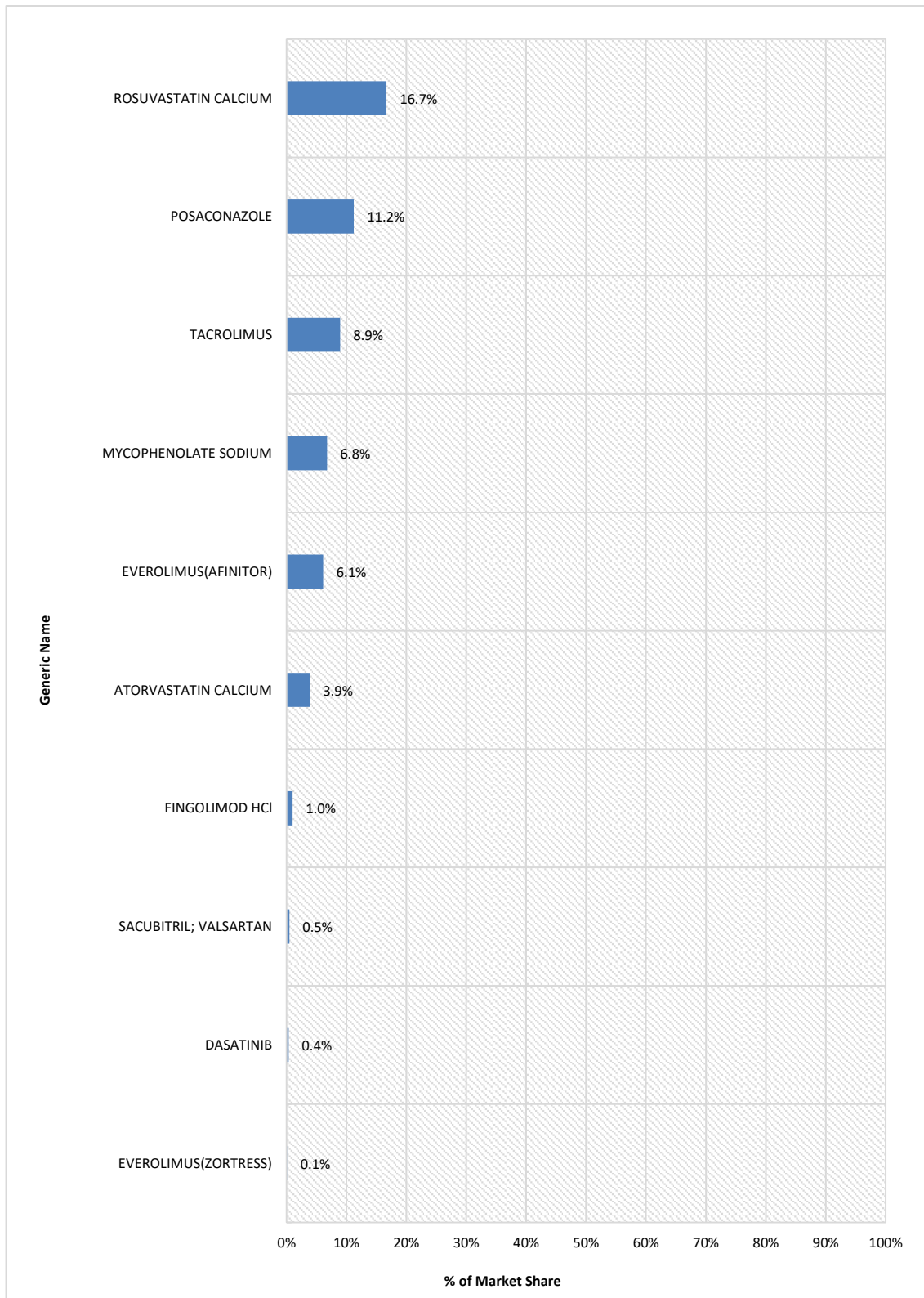
Biocon Biologics Received 5 Form 483 Observations (Pre-License Inspection): Moderate Risk to Approvals & Limited Generic Exposure

Biocon Biologics' biosimilars manufacturing complex at Biocon Park, Bengaluru, Karnataka, underwent a **Pre-License Inspection (PLI)** by the U.S. FDA from April 20, 2026 to April 29, 2026. The inspection covered 3 biologics manufacturing units, 5 quality testing laboratories, and 2 warehouses, and concluded with 5 observations issued in Form 483.

- **Facility Profile:** The Biocon Park manufactures biosimilars (**BLA**) and generic products (**ANDA**) for the U.S. market. The site produces a total of **15 generic products**, including oral solid and injectable formulations, supporting a broad and expanding biosimilars portfolio, including recently approved Denosumab (Bosaya and Vevzuo) biosimilars of Prolia and Xgeva.
- **Top Generic Products Manufactured:** Rosuvastatin Calcium, Atorvastatin Calcium, Everolimus, Sacubitril; Valsartan, Tacrolimus.
- **Products Likely Exposed to Shortages (Market Share >25%):** None identified based on current market share assessment.
- **Revenue Contribution:** The inspected facilities collectively generate approximately **\$44.67 Mn** in U.S. sales from generics (ANDA) only, representing around **76.36%** of Biocon's total U.S. generics revenue (excluding biosimilars).
- **Backup Coverage:** **~57% (\$25.3Mn)** of U.S. sales are supported by alternate manufacturing, while **~43% (\$19.4Mn)** remain exposed without backup coverage, indicating a moderate supply risk in case of disruption.
- **Inspection History:** Multiple USFDA inspections with outcomes of NAI, VAI, and a past OAI (2019), reflecting an overall improving compliance trend.

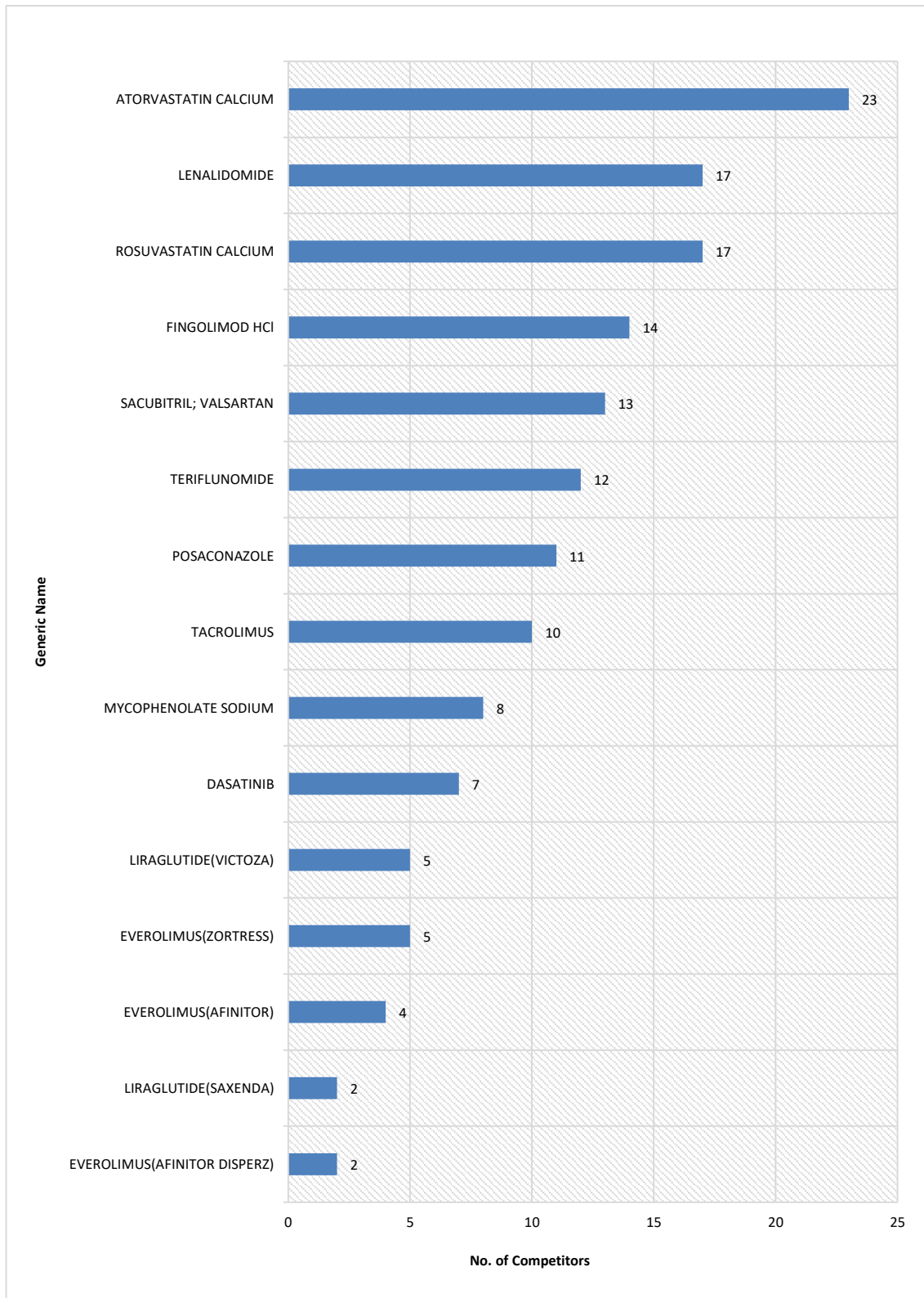
The observations are **procedural in nature**, with no data integrity or quality concerns and no repeat observations. As this was a Pre-License Inspection (PLI), timely **CAPA implementation** is critical for approvals; any delays could impact approval timelines and market entry. **Generic (ANDA) risk remains limited**, given lower market concentration and partial backup coverage.

CHART 1: BIOCON PRODUCT WISE MARKET SHARE



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

CHART 2: GENERIC COMPETITION



Number of competitors counted as of today in same RLD

Detailed Analyses



Impact Analysis: Biocon, Biocon Park, Bengaluru



TABLE 1: 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	207752	ROSUVASTATIN CALCIUM	CRESTOR	TABLET; ORAL	BIOCON	17	1)CARIBE HOLDINGS, PR, USA 2)RECIPHARM, BENGALURU, IND	-	15.13	25.86%	16.66%
2	216436	ATORVASTATIN CALCIUM	LIPITOR	TABLET; ORAL	BIOCON	23	1)NEOLPHARMA, PR, USA 2)RECIPHARM, BENGALURU, IND	Polymeric Compounds, M.W.> 1000 Da	10.12	17.31%	3.88%
3	214182	EVEROLIMUS	AFINITOR	TABLET; ORAL	BIOCON	4	-	-	5.70	9.75%	6.13%
4	213680	SACUBITRIL; VALSARTAN	ENTRESTO	TABLET; ORAL	BIOCON	13	-	-	5.34	9.13%	0.48%
5	212297	TACROLIMUS	PROGRAF	CAPSULE; ORAL	BIOCON	10	-	Naturally sourced ingredients	4.44	7.59%	8.94%
6	214630	MYCOPHENOLATE SODIUM	MYFORTIC	TABLET DR; ORAL	BIOCON	8	-	-	1.26	2.16%	6.76%
7	217217	DASATINIB	SPRYCEL	TABLET; ORAL	BIOCON	7	-	-	1.13	1.92%	0.36%
8	214476	POSACONAZOLE	NOXAFIL	TABLET DR ORAL	BIOCON	11	-	-	0.92	1.58%	11.22%
9	207979	FINGOLIMOD HCI	GILENYA	CAPSULE; ORAL	BIOCON	14	-	-	0.60	1.03%	1.01%
10	216140	EVEROLIMUS	ZORTRESS	TABLET; ORAL	BIOCON	5	-	-	0.02	0.03%	0.10%
11	215759	LENALIDOMIDE	REVLIMID	CAPSULE; ORAL	BIOCON	17	-	-	0.00	0.00%	0.00%
12	209639	TERIFLUNOMIDE	AUBAGIO	TABLET; ORAL	BIOCON	12	-	-	-	-	-
13	217216	EVEROLIMUS	AFINITOR DISPERZ	TABLET, FOR SUSPENSION; ORAL	BIOCON	2	-	-	-	-	-
14	217063	LIRAGLUTIDE	SAXENDA	SOLUTION; SUBCUTANEOUS	BIOCON	2	-	Peptide Compounds, Naturally sourced ingredients, M.W.> 1000 Da	-	-	-
15	215245	LIRAGLUTIDE	VICTOZA	SOLUTION; SUBCUTANEOUS	BIOCON	5	-	Peptide Compounds, Naturally sourced ingredients, M.W.> 1000 Da	-	-	-
									44.67	76.36%	

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 Biocon US Sales for ANDA is \$58.49 Mn

TABLE 2: INSPECTION HISTORY

FEI	Inspection End Date	Classification
3003981475	07/26/2024	Voluntary Action Indicated (VAI)
	08/30/2019	Voluntary Action Indicated (VAI)
	02/15/2019	Official Action Indicated (OAI)
3010164491	09/27/2024	Voluntary Action Indicated (VAI)
	01/24/2020	Voluntary Action Indicated (VAI)
3013637926	06/02/2023	No Action Indicated (NAI)
	01/17/2020	No Action Indicated (NAI)
	02/15/2019	No Action Indicated (NAI)

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