IMPACT ANALYSIS:
DR REDDY'S, PU 01, SRIKAKULAM

Dr. Reddy's Srikakulam Facility Receives Five USFDA Form 483 Observations: Important Facility, But Limited Risk due to Strong Backup for Most Products

02nd JAN 2026

RESEARCH DELTA

Impact Analysis: Dr Reddy's, PU 01, Srikakulam

02nd Jan 2026

Important Facility, But Limited Risk due to Strong Backup for Most Products

Dr. Reddy's Laboratories Limited operates the **CTO-SEZ Process Unit-01** located at **Devunipalavalasa Village, Ranastalam Mandal, Srikakulam, Andhra Pradesh 532409, India (IND)**. The facility was inspected by the **USFDA from December 4 to December 12, 2025**, as part of a **Pre-Approval Inspection (PAI)**, and the inspection concluded with the issuance of a **Form 483 containing five observations**.

- The site is a **strategically important manufacturing facility** within Dr. Reddy's U.S. generics network, supporting multiple high-value molecules and contributing company's **overall U.S. business**.
- The Srikakulam PU01 facility manufactures several important U.S.-marketed products, with annual sales > **$ 5 million**.
- **Four out of the five important products have backup manufacturing facilities**, materially lowering dependency on the Srikakulam site.
- **More than 60%** of the sales exposure linked to this facility is already backed up, mitigating the risk of sustained revenue disruption.
- In case of any supply disruptions due to GMP issues, we believe one drug which may face risk of shortages, driven by its relatively higher market share and the absence of an approved backup manufacturing facility.

Based on historical inspection outcomes, the site previously received a **VAI classification in October 2019**, followed by **NAI classifications in May 2018**, reflecting an overall track record of regulatory recoverability.

In conclusion, strong product-level backup coverage and a proven regulatory recovery track record are expected to limit business impact, provided timely corrective actions are implemented to address the five Form 483 observations.

Impact Analysis: Dr Reddy's, PU 01, Srikakulam

CHART 1: BREAKUP OF SALES WITH MARKET SHARE (>50% VS <50%)

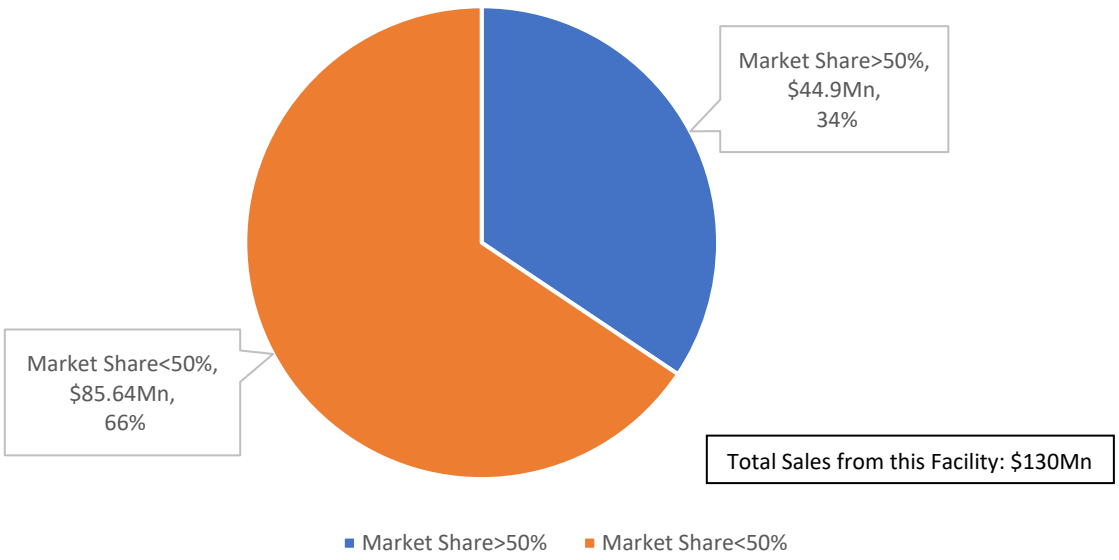


CHART 2: TOTAL PRODUCT SALES (WITH BACKUP FACILITY VS WITHOUT BACKUP FACILITY

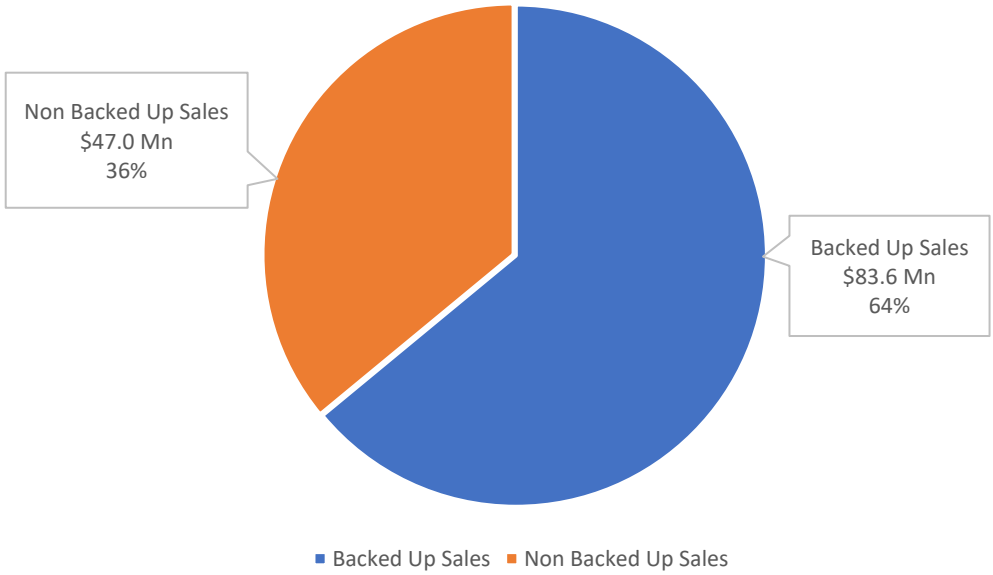
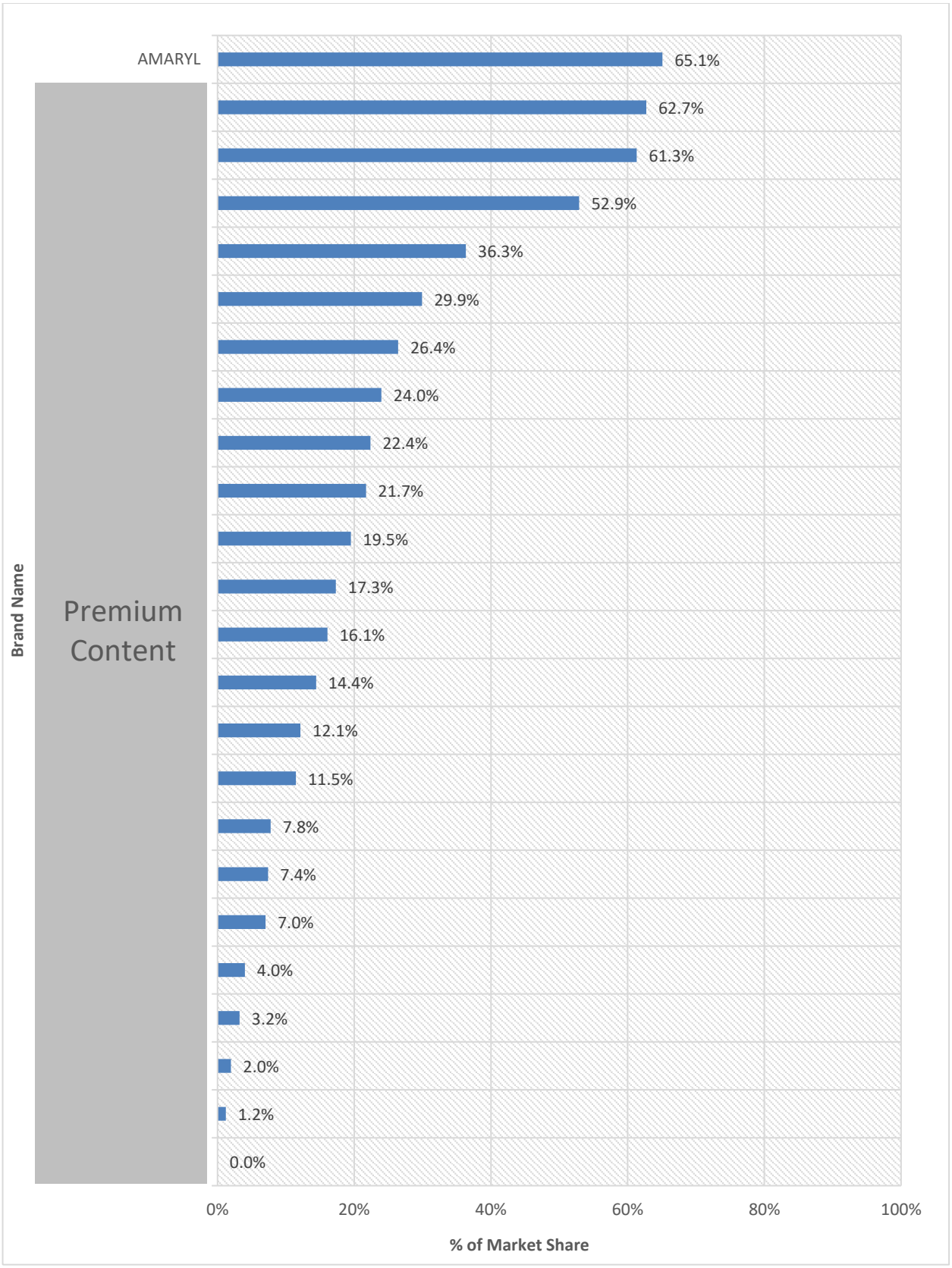
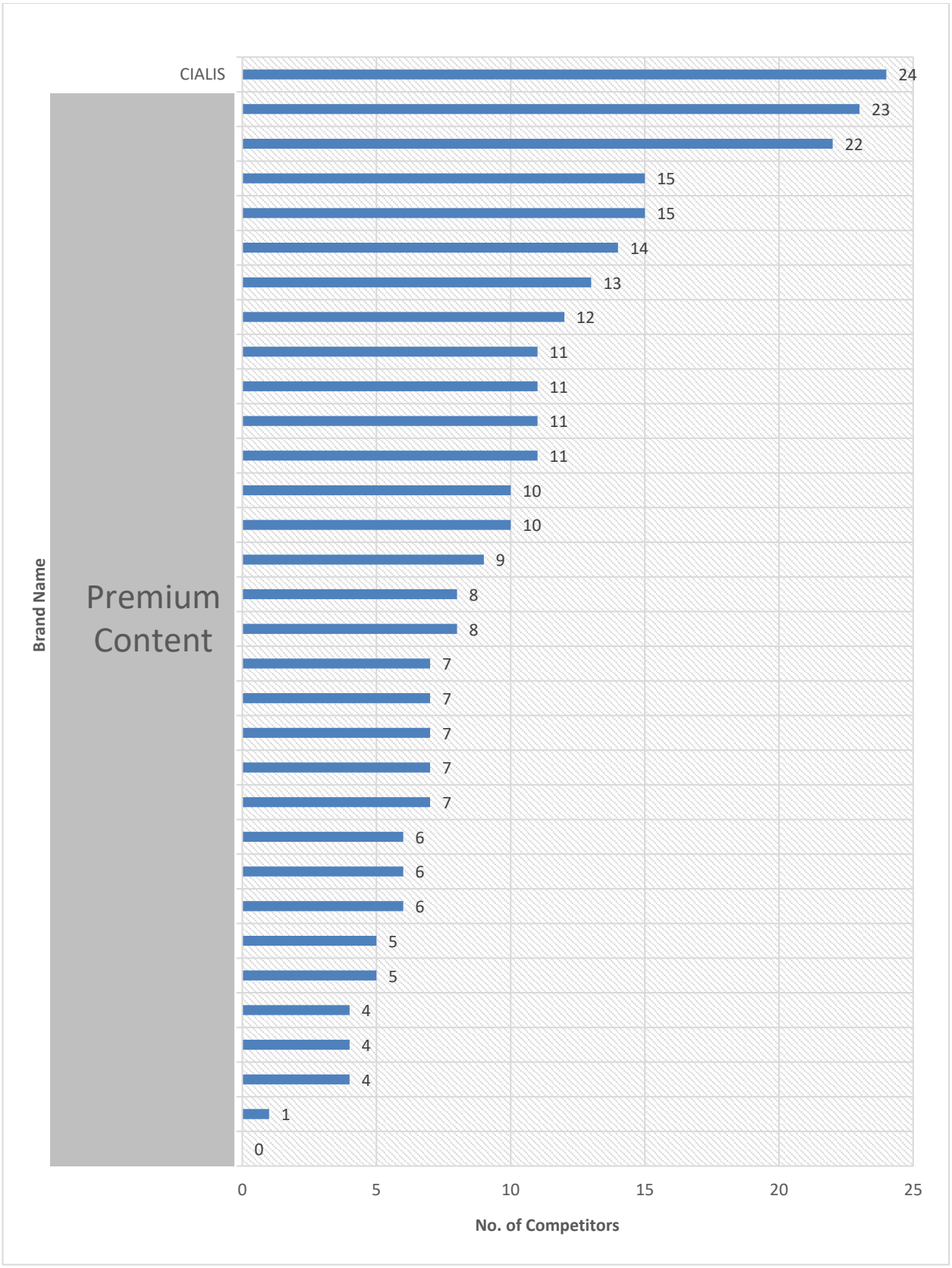


CHART 3: DR REDDY'S ANDA WISE MARKET SHARE



Note: Market share calculated based on 12 months sale ended in Q4-2024

CHART 4: GENERIC COMPETITION



No of competitors counted as of today

Detailed Analyses

Impact Analysis: Dr Reddy’s, PU 01, Srikakulam

RESEARCH DELTA

TABLE 1: GENERIC PRODUCTS

Sr. No.	ANDA ApplNo	Generic Name	Brand Name	Dosage; Form	ANDA Owner	Other Gx competi-tors	Other Facility for same ANDA	Complexity	Sales CY24 (IN USD MN)	% of Dr Reddy's US Sales	Dr Reddy's Market Share
1	076286	TIZANIDINE HCL	ZANAFLEX	TABLET; ORAL	DR REDDY'S	9	1) Dr Reddy's, Bachupally 2)Northstar Medical, Wisconsin, USA	-	**31.93**	**3.6%**	**62.7%**
2											
3											
4											
5											
6											
7											
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10											
11											
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20											

Premium Content

Sr. No.	ANDA ApplNo	Generic Name	Brand Name	Dosage; Form	ANDA Owner	Other Gx competi-tors	Other Facility for same ANDA	Complexity	Sales CY24 (IN USD MN)	% of Dr Reddy's US Sales	Dr Reddy's Market Share
21											
22											
23											
24											
25											
26											
27											
28											
29											
30											
31											
32											
33											

Premium Content

Source: - GenUS, Research Delta Advisors
Note: Sales as per Medicaid Drug Rebate Program (Q1-Q4 FY2024)
Market share based on total revenue of therapeutically equivalent NDA and ANDAs

TABLE 2: INSPECTION HISTORY

Inspection End Date	Classification
11/14/2025	No Action Indicated (NAI)
10/25/2019	Voluntary Action Indicated (VAI)
05/31/2018	No Action Indicated (NAI)
04/14/2017	No Action Indicated (NAI)

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