IMPACT ANALYSIS:
AUROBINDO PHARMA, UNIT VII

Revenue-Critical Site Faces Heightened Regulatory Watch

14th FEB 2026

RESEARCH DELTA

14th Feb 2026

Aurobindo Pharma's Unit–VII Receives 9 Form 483 Observations: Revenue-Critical Site Faces Heightened Regulatory Watch

The U.S. Food and Drug Administration (USFDA) inspected Aurobindo Pharma's Unit–VII, an oral solid dosage manufacturing facility located at Plot S1 Part SEZ, TSIIC Green Industrial Park, Polepally, Jedcherla Mandal, Mahabubnagar, Telangana, India, from **January 28 to February 10, 2026**. The inspection concluded with issuance of a Form 483 containing **9 observations**.

• **Product Profile:** Total **209** products are manufactured at this facility; **6** are currently discontinued and **2** are branded drugs. Additionally, [redacted] products have backup manufacturing facilities.

• **Revenue Contribution:** The facility contributes **~51%** of Aurobindo's total US sales*, making it a strategically critical site for the company's US generics portfolio.

• **Backup Coverage:** Approximately [redacted]**%** of the facility's US revenue is supported by alternate manufacturing sites.

• **Regulatory Context:** Issuance of **9** Form 483 observations indicates compliance gaps requiring remediation; final FDA classification (NAI/VAI/OAI) is pending. Prior NAI status on 08-04-2023 suggests historically acceptable compliance standards.

• **Products Likely Exposed to Shortages:** (Based on Market Share >25%, No Backup manufacturing and Sales* >$3Mn)**:** Generics of [redacted]

• **Financial Impact:** While facility concentration is high, strong backup manufacturing coverage reduces consolidated revenue risk; however, compound-level exposure could be meaningful in high-market-share products lacking alternate supply.

If observations are resolved within standard remediation timelines, impact is expected to remain manageable. However, escalation to VAI/OAI classification, Warning Letter, or import-related restrictions could materially increase supply chain, revenue, and competitive risks.

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 (Q3-Q4 FY2024, Q1-Q2 FY2025)

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 Company's US Sales*	Market Share*
1											
2											
3											
4											
5											
6											
7											
8											
9	205762	ETHINYL ESTRADIOL; NORGESTIMATE	ORTHO TRI-CYCLEN LO	TABLET; ORAL-28	AUROBINDO	6	-	-	3.44	**0.16%**	53.1%
									136.66	**6.56%**	

Source: GenUS Database, 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 (Q3-Q4 FY2024, Q1-Q2 FY2025)

CHART 1: PRODUCT SALES

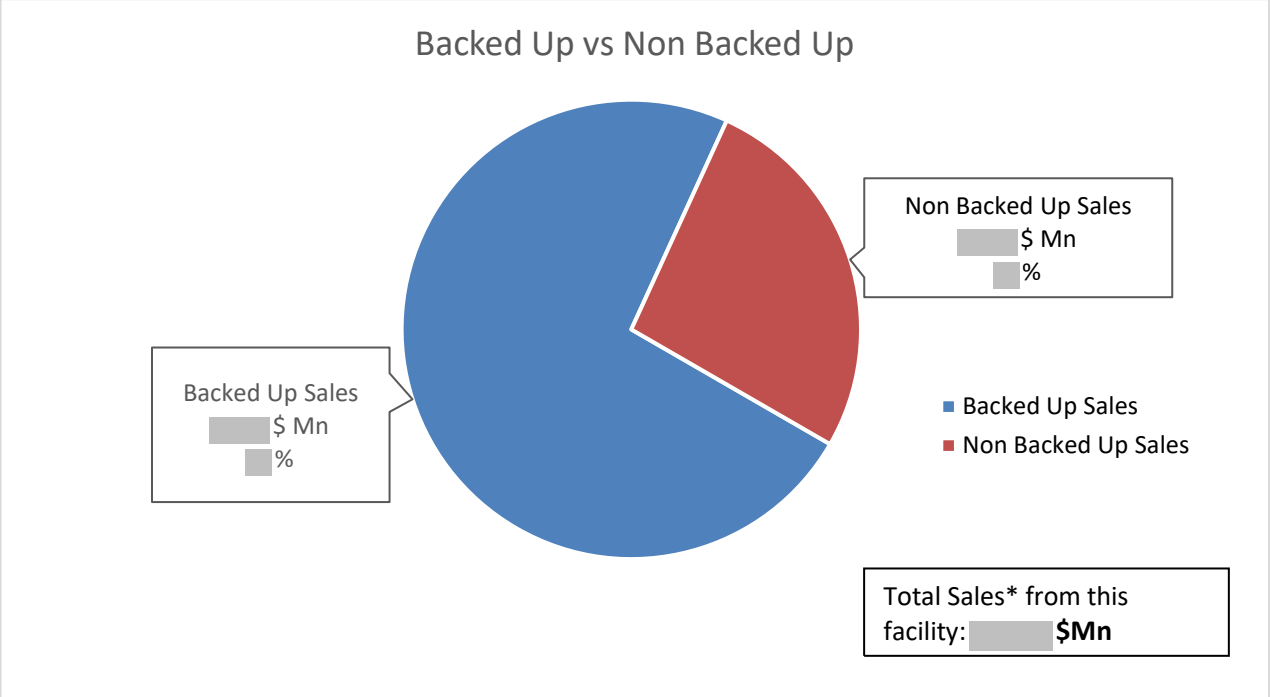


CHART 2: BREAKUP OF SALES WITH MARKET SHARE

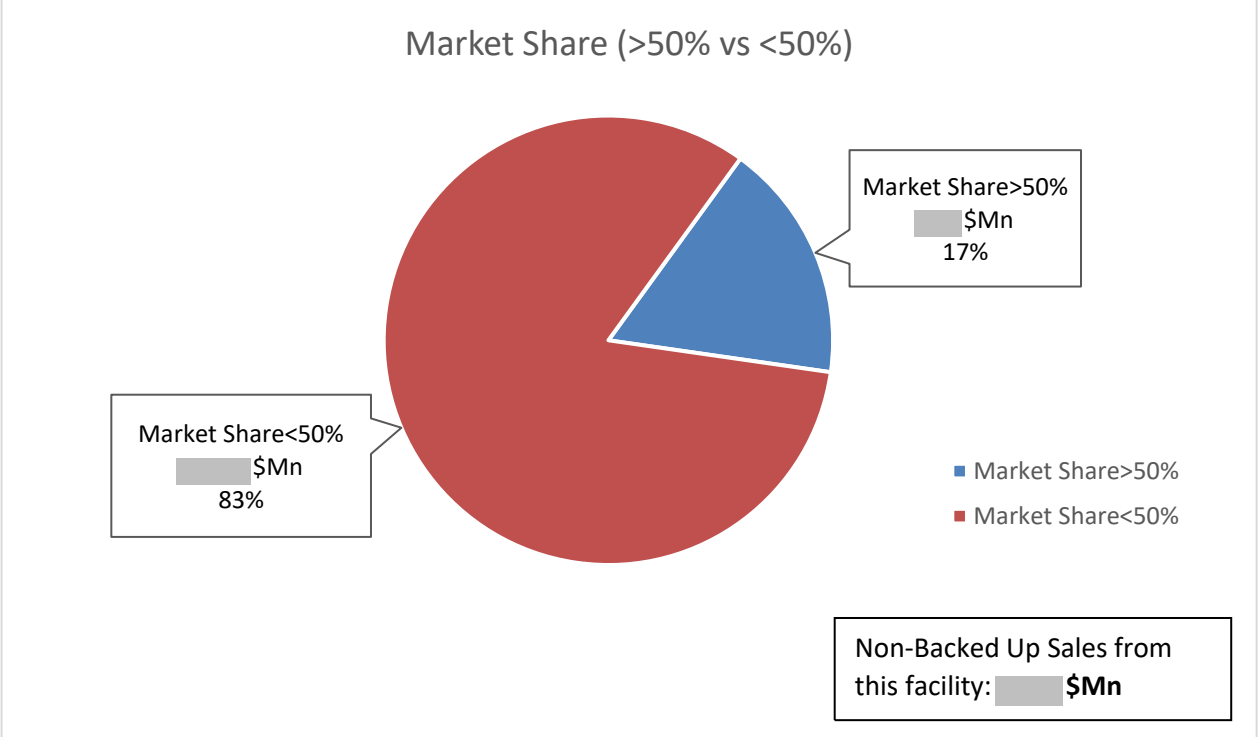
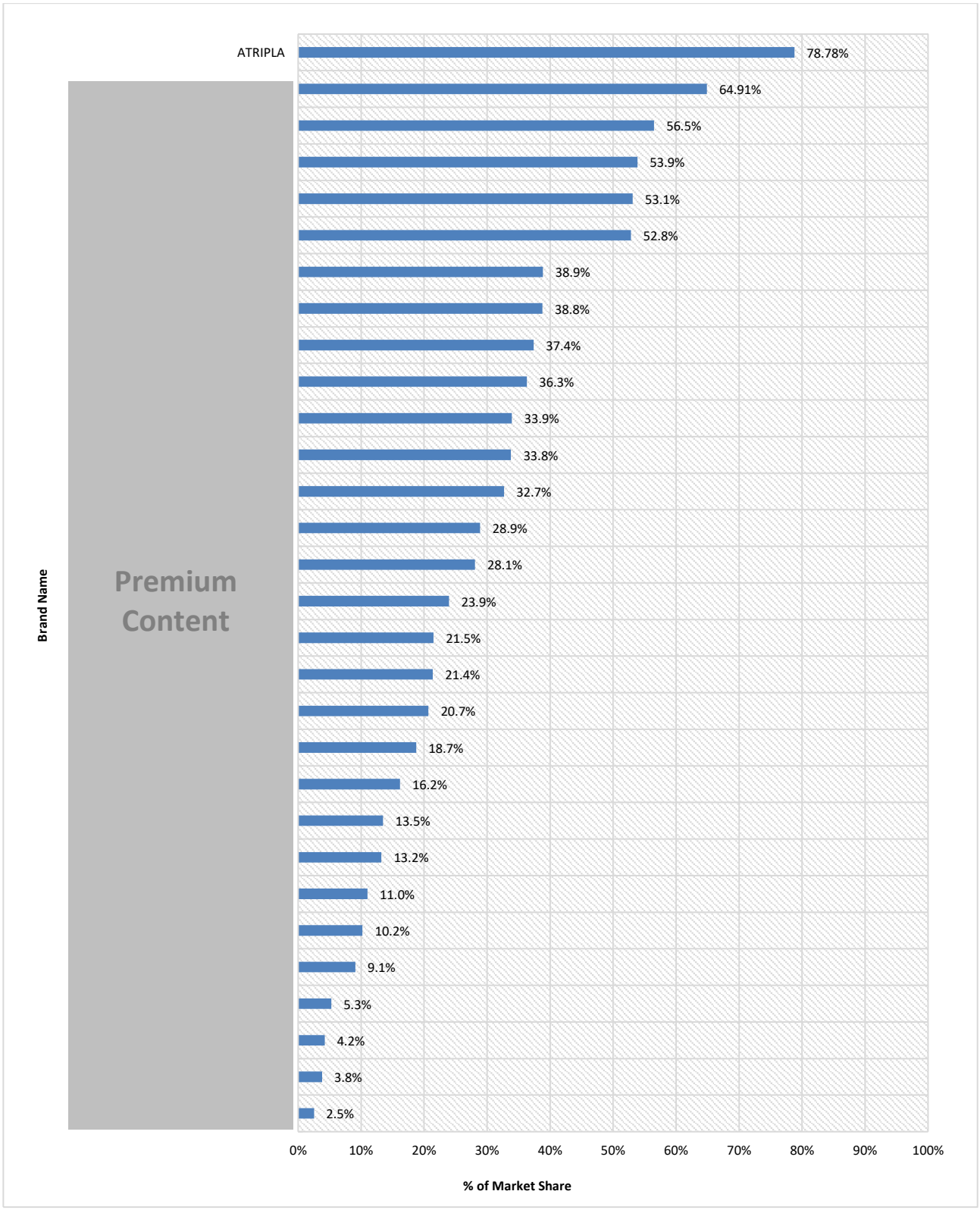
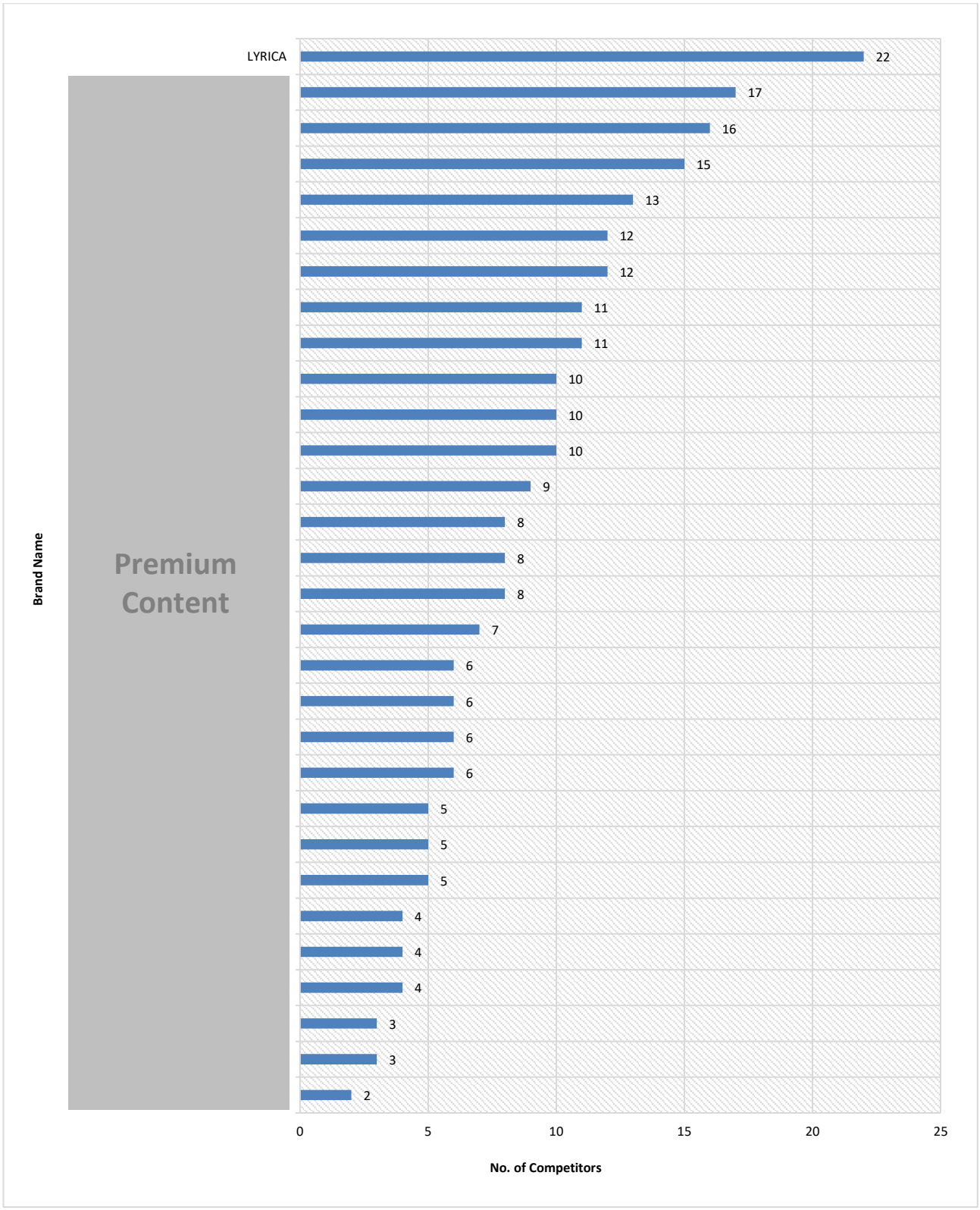


CHART 3: AUROBINDO PHARMA PRODUCT WISE MARKET SHARE



Note: Market share* calculated based on 12 months sale ended in Q2-2025, In above chart only drugs are considered with Sales*>2$ Mn and No Backup manufacturing site.

CHART 4: GENERIC COMPETITION



Note: No of competitors counted as of today. In above chart only drugs are considered with Sales*>2$ Mn and No Backup manufacturing site.

Detailed Analyses

TABLE 2: ALL 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 Company's US Sales*	Market Share*
1	213794	IBUPROFEN	MOTRIN	TABLET; ORAL	AUROBINDO	12	1) APL Healthcare, Unit-I, India	-	**64.11**	**3.08%**	**28.8%**

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 (Q3-Q4 FY2024, Q1-Q2 FY2025)
*Red text drugs are currently Discontinued according to FDA
*Orange text NDA: New Drug Application (Branded Drug)

TABLE 3: INSPECTION HISTORY

Inspection End Date	Classification
08-04-2023	No Action Indicated (NAI)
05-10-2022	Voluntary Action Indicated (VAI)
09-27-2019	Official Action Indicated (OAI)

Thank you for reading this preview edition.
The premium edition includes detailed analysis of **209** products, and complete data breakdowns for strategic decision-making.