

IMPACT ANALYSIS: AUROBINDO PHARMA, UNIT XII

β -lactam Antibiotic Facility with Several Market Leading Products

11th SEP 2025



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Aurobindo Pharma Receives 8 USFDA Observations:

β -lactam Antibiotic Facility with Several Market Leading Products

The USFDA conducted an inspection of Aurobindo Pharma's Unit XII facility located at Sy.No.314 Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Medchal, Telangana 500090, India (IND) from 25 August and 5 September 2025. At the conclusion of the inspection, the agency issued a Form 483 with eight observations.

1. This facility manufactures several generic products (oral and injectables). All the products belong to the β -lactam class of Antibiotics.
2. Many of the injectable products and some of the oral products are backed up by Eugia's facility.
3. The site generates sizeable revenue in annual sales. Of these many products are backed up by another facility.
4. Many of the market leading products are backed up by another facility.
5. Being β -lactam antibiotics facility, most products are manufactured through naturally sourced ingredients.

While the observations are yet to be known, the facility is exposed to the risk of contamination as it manufactures several injectable products. Given the higher number of observations, remediation may take longer time with a constant risk of escalation of GMP issues.

In case of any supply disruption (due to remediation/GMP escalation), significant portion of US sales is at stake. A supply disruption would also mean possible drug shortages in some market leading products.

CHART 1: Market Share- <50% vs >50%

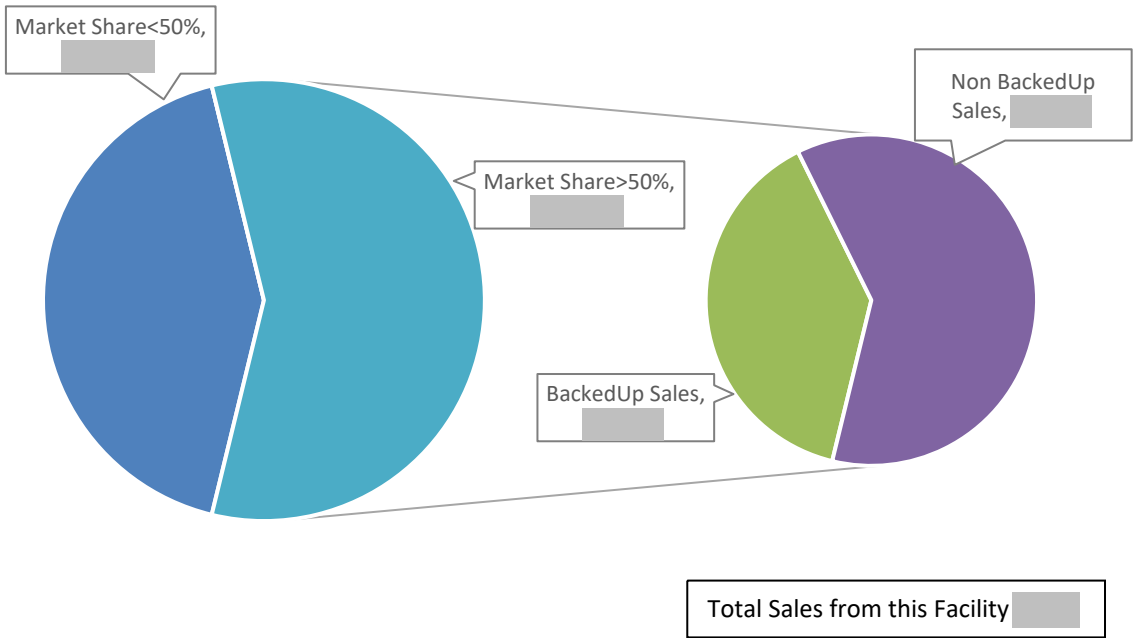


Chart 2: Product Sales- Backed Up vs Non Backed Up

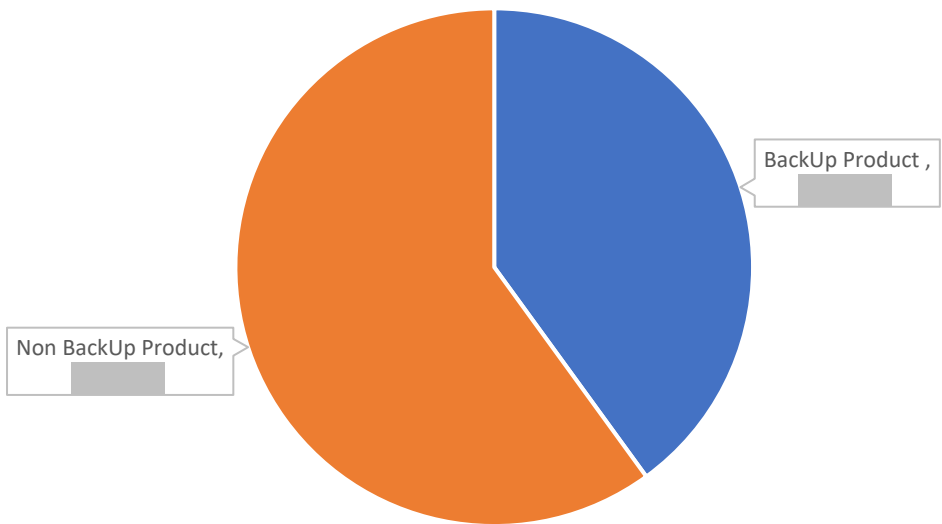
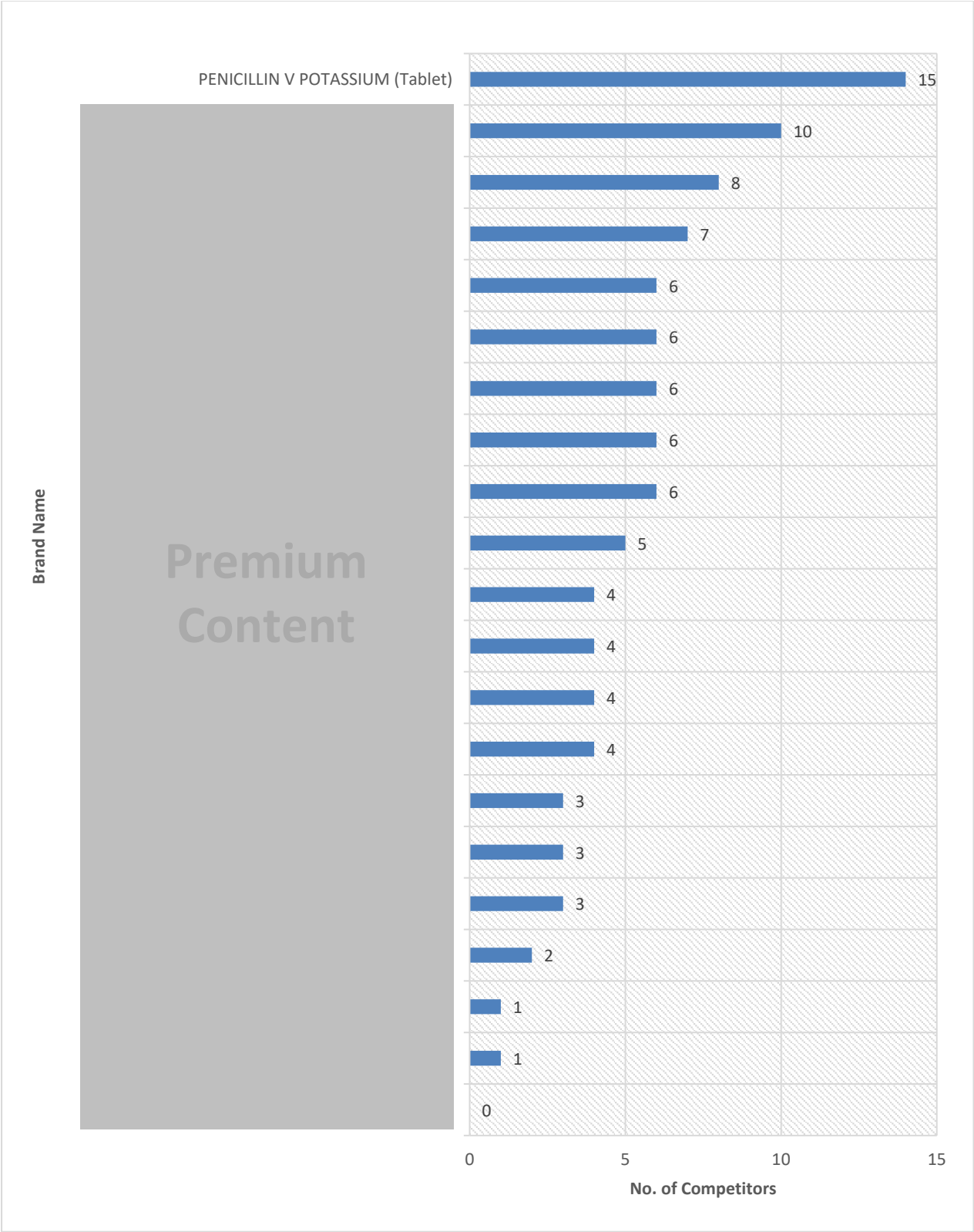
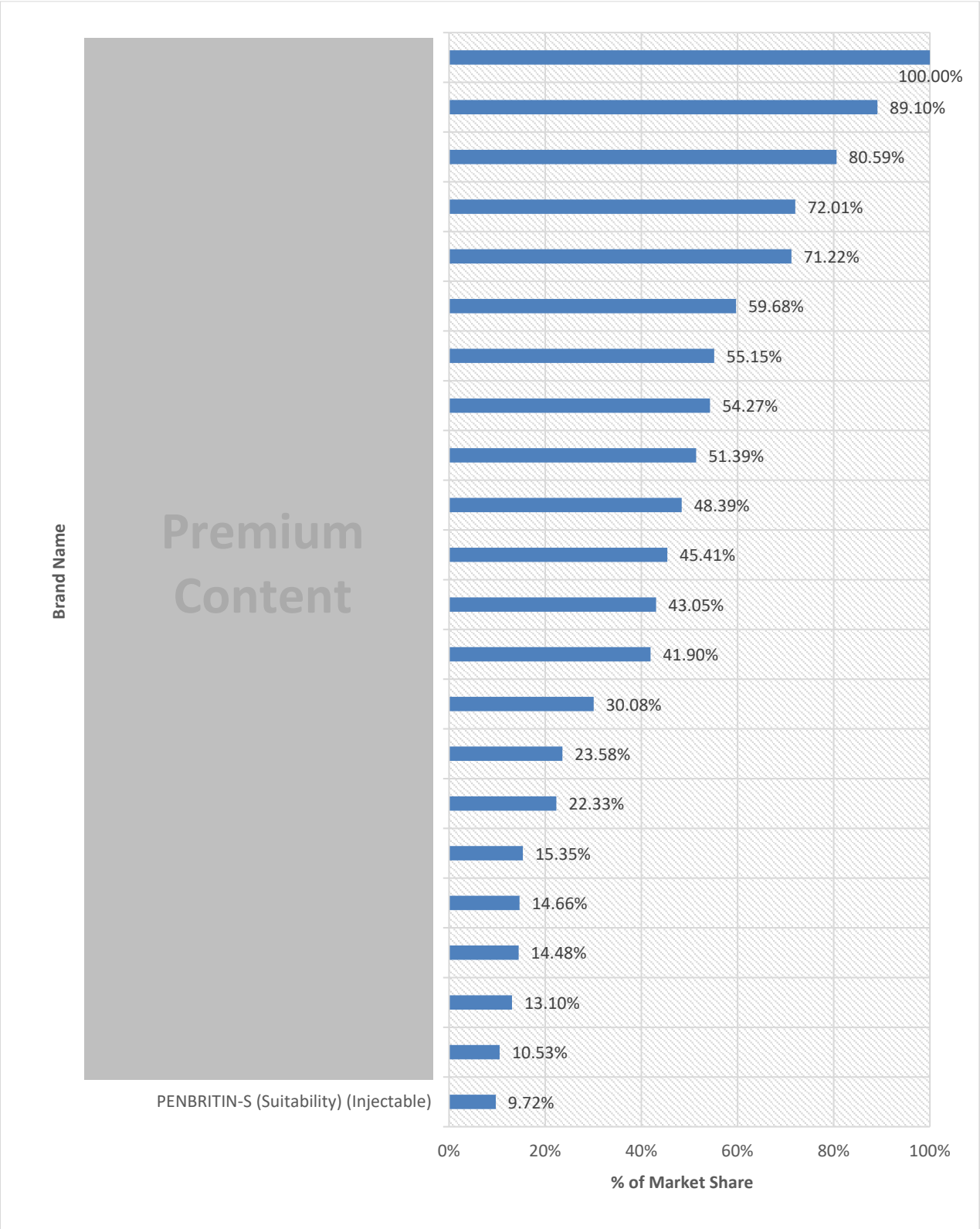


CHART 3: GENERIC COMPETITION



No of competitors counted as of today

CHART 4: AUROBINDO PHARMA’S ANDA WISE MARKET SHARE



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

Detailed Analyses





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 Aurobindo's US Sales	Aurobindo's Market Share
1	65334	AMOXICILLIN	AMOXIL	SUSPENSION; ORAL	AUROBINDO	4	-	Naturally sourced ingredient	49.71	2.4%	30.08
2	<div>Premium Content</div>										
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											

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



TABLE 1: GENERICS 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 Aurobindo's US Sales	Aurobindo's Market Share
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
								Total			

Source: - GenUS, Research Delta Advisors
Note: Sales as per Medicaid Drug Rebate Program
Market share based on total revenue of therapeutically equivalent NDA and ANDAs
*Approval of this product is currently discontinued

TABLE 2: INSPECTION HISTORY

Inspection End Date	Classification
03-09-2023	Voluntary Action Indicated (VAI)
02-21-2020	Voluntary Action Indicated (VAI)
03-16-2018	Voluntary Action Indicated (VAI)

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