

# **IMPACT ANALYSIS: NATCO PHARMA, KOTHUR, HYDERABAD**

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24<sup>th</sup> JUNE 2025



24<sup>th</sup> June 2025

## Natco Pharma's Kothur Facility Receives Form 483 with 7 Observations

### Lenalidomide at "Significant Risk" of Supply Disruption

The U.S. Food and Drug Administration (USFDA) conducted a GMP inspection of Natco Pharma Limited's Kothur facility, located in Kothur Village, Rangareddy, Telangana 509 228, India, from June 9 to 19, 2025. The facility is already under **Warning Letter**.

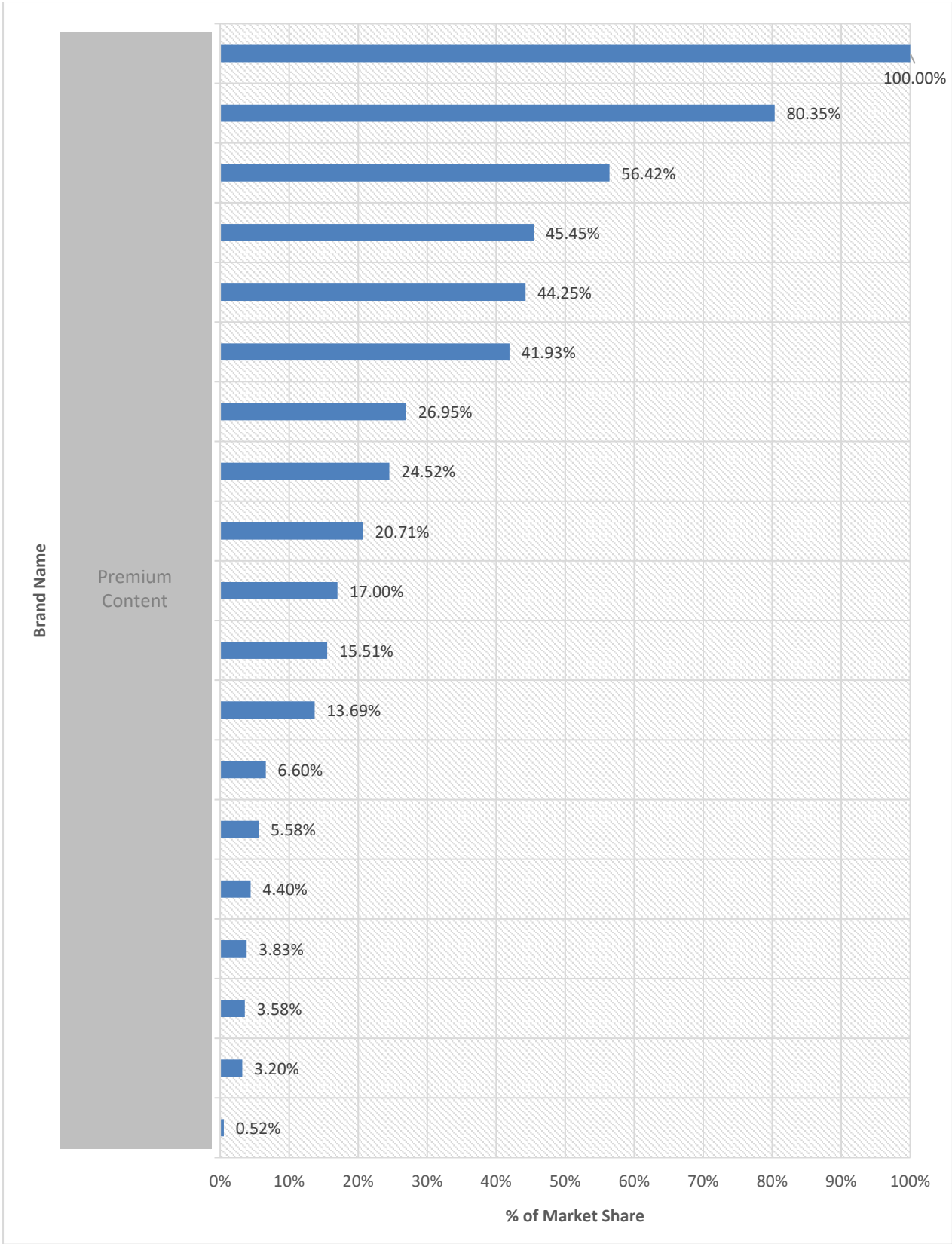
Following the inspection, the agency issued a Form 483 containing **7 observations**, signalling potential quality or procedural concerns.

1. This is a key facility for Natco, as 20 ANDAs are solely manufactured in this facility including Lenalidomide. 7 ANDAs are manufactured in both the facilities (Kothur and SEZ facilities). In summary, it manufactures 27 of the 28 ANDAs representing **~98%** of Natco's total sales
2. One of the most important products manufactured in this facility represents **~78%** of Natco's total sales.
3. The chances of disruptive remediations are high given that the facility is already under **Warning Letter** and with 7 observations, the company might be forced to take drastic remediation measures that may likely disrupt production.
4. All other products (other than key products) are modest in sales with only 2 products clocking sales of more than \$5 Mn annually.
5. 19 out of total 26 products manufactured at this facility are facing competition from more than 5 generic manufacturers.

In terms of revenue impact, this facility contributes **~98%** of total Natco US sales (including partnered products) and **~82%** of total from products not backed by another facility.

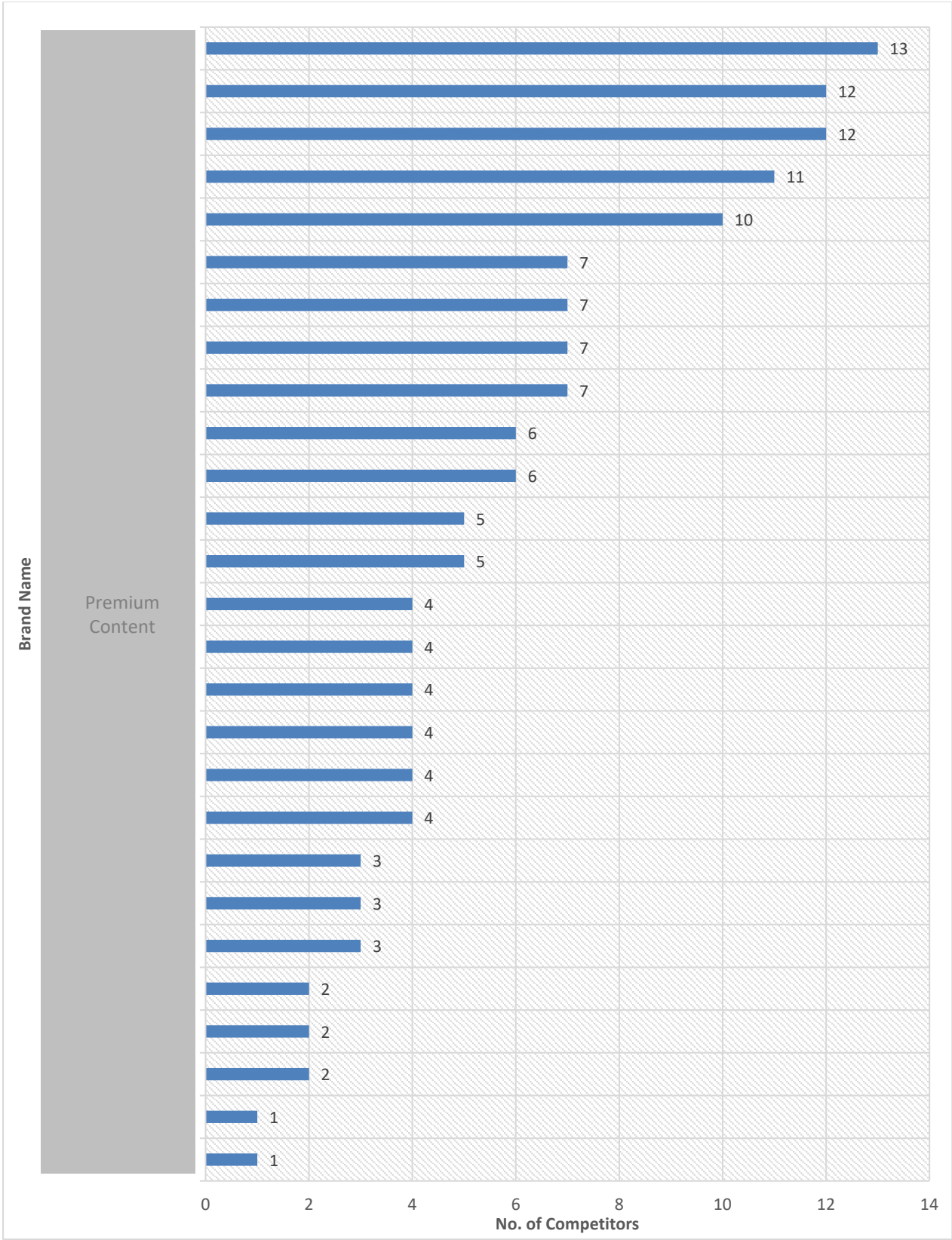


**CHART 1: NATCO PHARMA’S PRODUCT WISE MARKET SHARE**



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

CHART 2: PRODUCT WISE COMPETITION LANDSCAPE



No of competitors counted as of today

## ***Detailed Analyses***

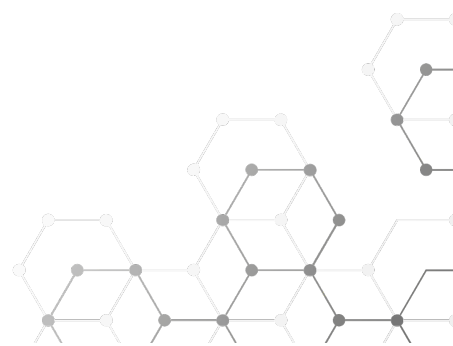


TABLE 1: LOW COMPETITION PRODUCTS

Sr No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other ANDA Developers	Other Facility for same ANDA	Complexity	Sales CY24 (in USD MN)	% of NATCO Pharma US Sales	Market Share
1	90978	LANTHANUM CARBONATE	FOSRENOL (Tablet,Chewable)	NATCO	BARR, INVAGEN PHARMA, ALKEM	-	1) NATCO, ANAKAPALLI, ANDHRA PRADESH	-	5.3	4.0%	80.4%
2	<div>Premium Content</div>										
3											
4											
5											
6											
7											
8											
Total											

Source: - GenUS, Research Delta Advisors  
Note: Sales as per Medicaid Drug Rebate Program  
Market share is ANDA’s share of total generic sale of respective RLD

TABLE 2: COMMODITIZED PRODUCTS

Sr No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other Facility of NATCO Pharma for same ANDA	Sales CY24 (IN USD MN)	% of NATCO Pharma US Sales	Market Share
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
Total									

Source: - GenUS, Research Delta Advisors  
Note: Sales as per Medicaid Drug Rebate Program  
Market share is ANDA’s share of total generic sale of respective RLD

**TABLE 3: KOTHUR FACILITY INSPECTION HISTORY**

Date	Classification
24-01-2017	Voluntary Action Indicated (VAI)
06-06-2019	Voluntary Action Indicated (VAI)
24-06-2019	Voluntary Action Indicated (VAI)
06-03-2020	Voluntary Action Indicated (VAI)
08-04-2024	Warning Letter