

IMPACT ANALYSIS: HETERO PHARMA, UNIT IX, API FACILITY

Serious Observations Will Impact Formulation Business Too

27th NOV 2025



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Hetero Pharma Unit IX API Facility Received Six Form 483 Observations

Serious Observations Will Impact Formulation Business Too

Hetero Labs' **Nakkapalli API manufacturing facility** in Andhra Pradesh was inspected by the **USFDA between September 19 and September 26**, results in a Form 483 that lists **six major compliance lapses**. The inspection flagged serious violations.

This inspection uncovered widening gaps in Hetero's quality systems. Finished APIs meant for the US market were dispatched to an external warehouse without proper documentation. Inspectors also identified an **unregistered testing laboratory** and an unregistered warehouse operating outside the approved premises.

Given the seriousness of USFDA observations, a severe and widespread action is highly likely which may result in an Import Alert.

- The reviewed list includes 24 APIs manufactured at Unit IX, of which 16 are antiretroviral (ARV) drugs—key for HIV/AIDS treatment regimens. The site plays a critical role in the company's global supply chain.
- Remaining APIs serve diverse therapeutic segments, including cardiovascular, neurological, and psychiatric indications.
- We analysed the impact of Unit IX (APIs) on Hetero's US formulation business, assuming that Hetero is fully dependent upon the APIs from Unit IX for the manufacture of its related generic formulations. In light of that, Unit IX indirectly impacts 20 products (12 ARV and 8 non ARVs).
- In terms of revenues, the formulation products (dependant on Unit IX APIs) represent a sizeable portion of Hetero's own US formulation sales.
- Of all the formulation products, 12 products hold more than 25% market share. Of the 12 products, 2 products have sales of more than \$5m – which may likely result in shortages in the US if supply gets disrupted.
- In addition to the US, Hetero also supplies ARV products to the African countries. A significant part of that revenue is generated through purchases by the African countries funded by the US government and requiring USFDA approval for each product. In other words, the impact of Unit IX could also be seen on generic ARV business to African markets – though we are unaware about its market share.

TABLE 1: API MANUFACTURE AT HETERO’S UNIT IX FACILITY

ANTIRETROVIRAL (ARV)	NON-ANTIRETROVIRAL (NON -ARV)
1. Abacavir sulfate	1. Atorvastatin calcium (lipid-lowering)
Premium Content	Premium Content
Total ARVs: 16	Total Non ARVs: 8

Source: Hetero company reports

Total API manufactured at Hetero’s Unit IX facility = 24

TABLE 2: LIST OF HETERO’S FORMULATIONS RELATED TO APIs FROM UNIT IX

ANTIRETROVIRAL (ARV)			
	ANDA ApplNo	Generic Name	API
1	091560 & 201107	ABACAVIR SULFATE	ABACAVIR SULFATE
2	Premium Content		
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

NON-ANTIRETROVIRAL (NON -ARV)			
	ANDA ApplNo	Generic Name	API
1	214344	ATORVASTATIN CALCIUM	ATORVASTATIN CALCIUM
2	Premium Content		
3			
4			
5			
6			
7			

Source: - GenUS, Research Delta Advisors

CHART 1.1: GENERIC COMPETITION IN ARVs

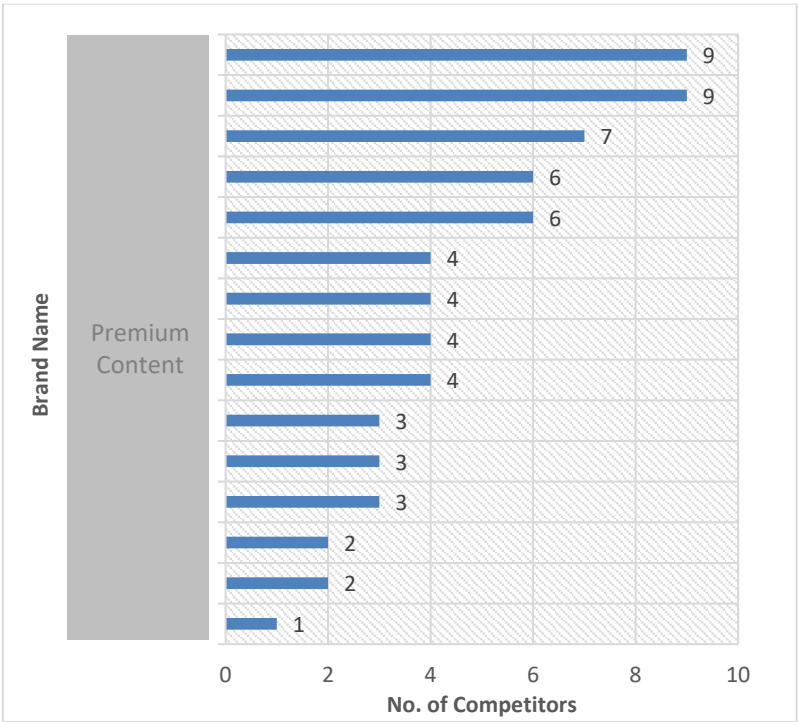
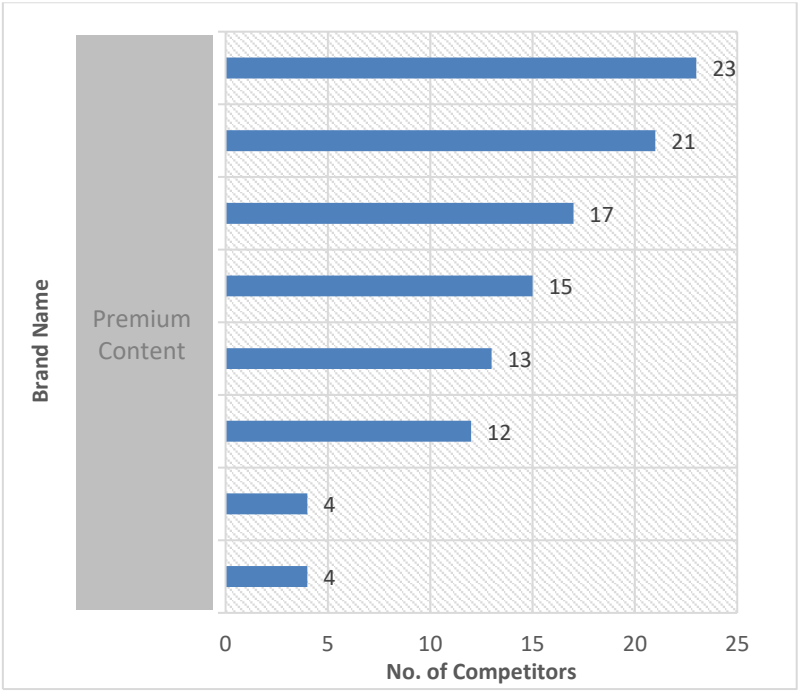


CHART 1.2: GENERIC COMPETITION IN NON ARVs



No of competitors counted as of today
Source: - GenUS, Research Delta Advisors

CHART 2.1: ARV PRODUCT MARKET SHARE

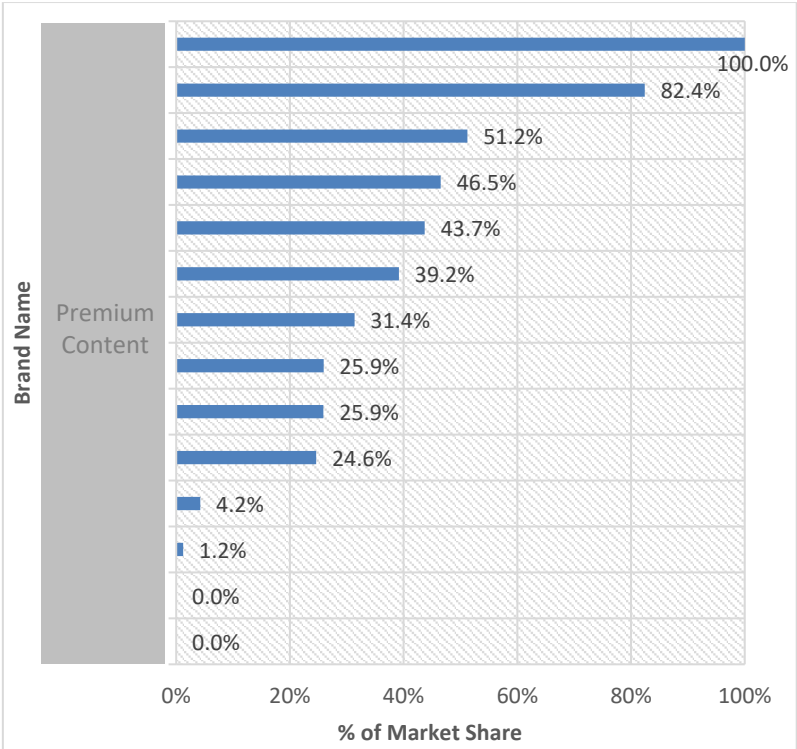
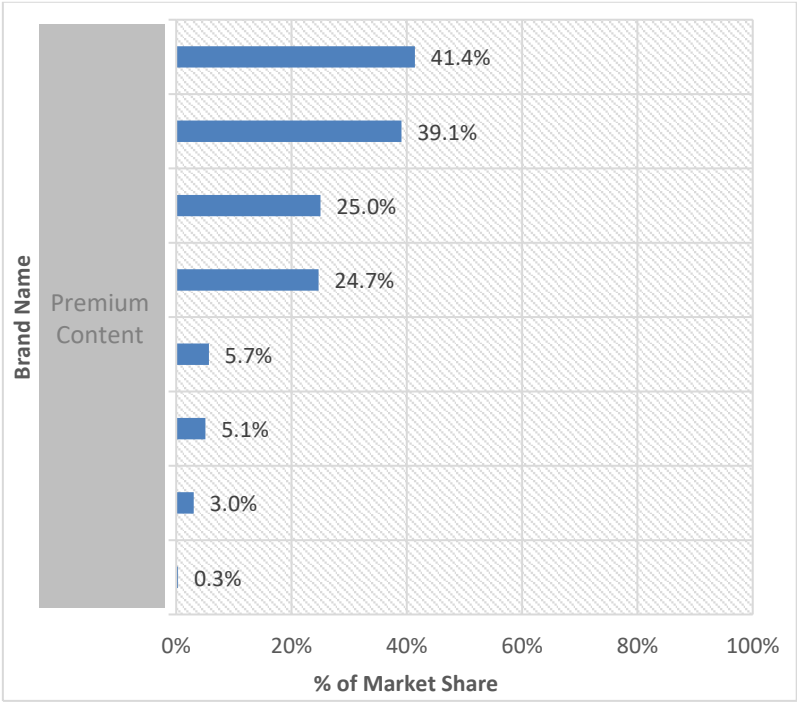


CHART 2.2: NON-ARV PRODUCT MARKET SHARE



Note: Market share calculated based on 12 months sale ended in Q4-2024
Source: - GenUS, Research Delta Advisors

Detailed Analyses

Impact Analysis: Hetero Pharma, Unit IX



TABLE 1: LIST OF ANTIRETROVIRAL (ARV) PRODUCTS

Sr. No.	ANDA ApplNo	Generic Name	Brand Name	Dosage Form	ANDA Owner	Other Gx competitors	Manufacturing Facility	Complexity	Sales CY24 (IN USD MN)	% of Hetero's US Sales	Hetero's Market Share
1	201806	EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE	TRUVADA	TABLET; ORAL	HETERO	3	1) Hetero, Unit III, Hyderabad	-	1.79	0.38%	4.2%
2	<div>Premium Content</div>										
3											
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12											
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14											
15											
								Total	<div></div>	<div></div>	

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

Impact Analysis: Hetero Pharma, Unit IX



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1	090515	LEVETIRACETAM	KEPPRA	TABLET; ORAL	HETERO	17	1) Hetero, Unit III, Hyderabad 2) Hetero, Kolar, Karnataka 3) Annora Pharma, Sangareddy	-	34.59	7.39%	41.4%
2	<div>Premium Content</div>										
3											
4											
5											
6											
7											
8											

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 3: INSPECTION HISTORY OF UNIT IX

Inspection End Date	Inspection Classification
11-08-2022	Voluntary Action Indicated (VAI)
05-14-2019	Official Action Indicated (OAI)
08-18-2017	Voluntary Action Indicated (VAI)
09-29-2014	Voluntary Action Indicated (VAI)
12-15-2011	No Action Indicated (NAI)

-----End of the report-----