



Impact Analyses: Unichem, Goa

July 17, 2024

Unichem Laboratories announced its Goa facility received 'Form 483' with five observations.

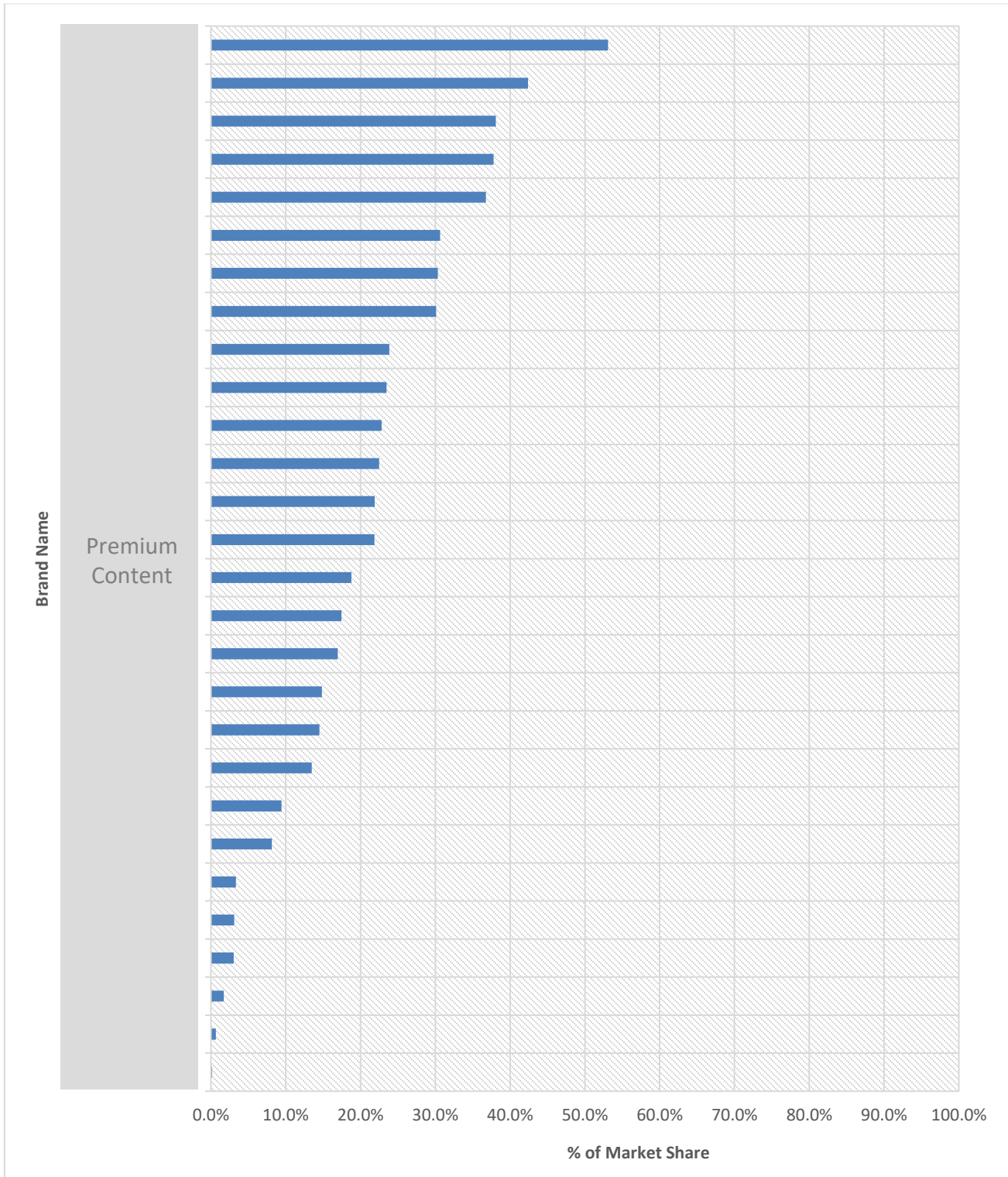
Unichem Laboratories Ltd. in its press release announced that, its Goa facility (Plot No. 10 to 18, Pilerne Industrial Estate, Pilerne, Bardez, Goa, India) received 'Form 483' with five observations. This is 1 of 2 USFDA approved facilities owned by the company. Unichem manufactures █ of the total 58 formulation products manufactured for the US market. This facility manufactures Oral Solids.

1. █ of the top █ products manufactured by Unichem for US market are manufactured in this facility.
2. █ out of total █ products manufactured at this facility are high competition products.
3. █ of the products manufactured at this facility are backed by other facilities.
4. 2 of the Products manufactured at this facility are partnered/contract manufactured products.

In terms of revenue impact, this facility contributes ~5% (excluding sales of the products backed by other facilities) of total Unichem's US sales (including partnered products). The facility has been under 'VAI' status since 2009. Given the █ contribution to overall sales, the worst-case impact on revenue (assuming an import alert) is likely to be █.

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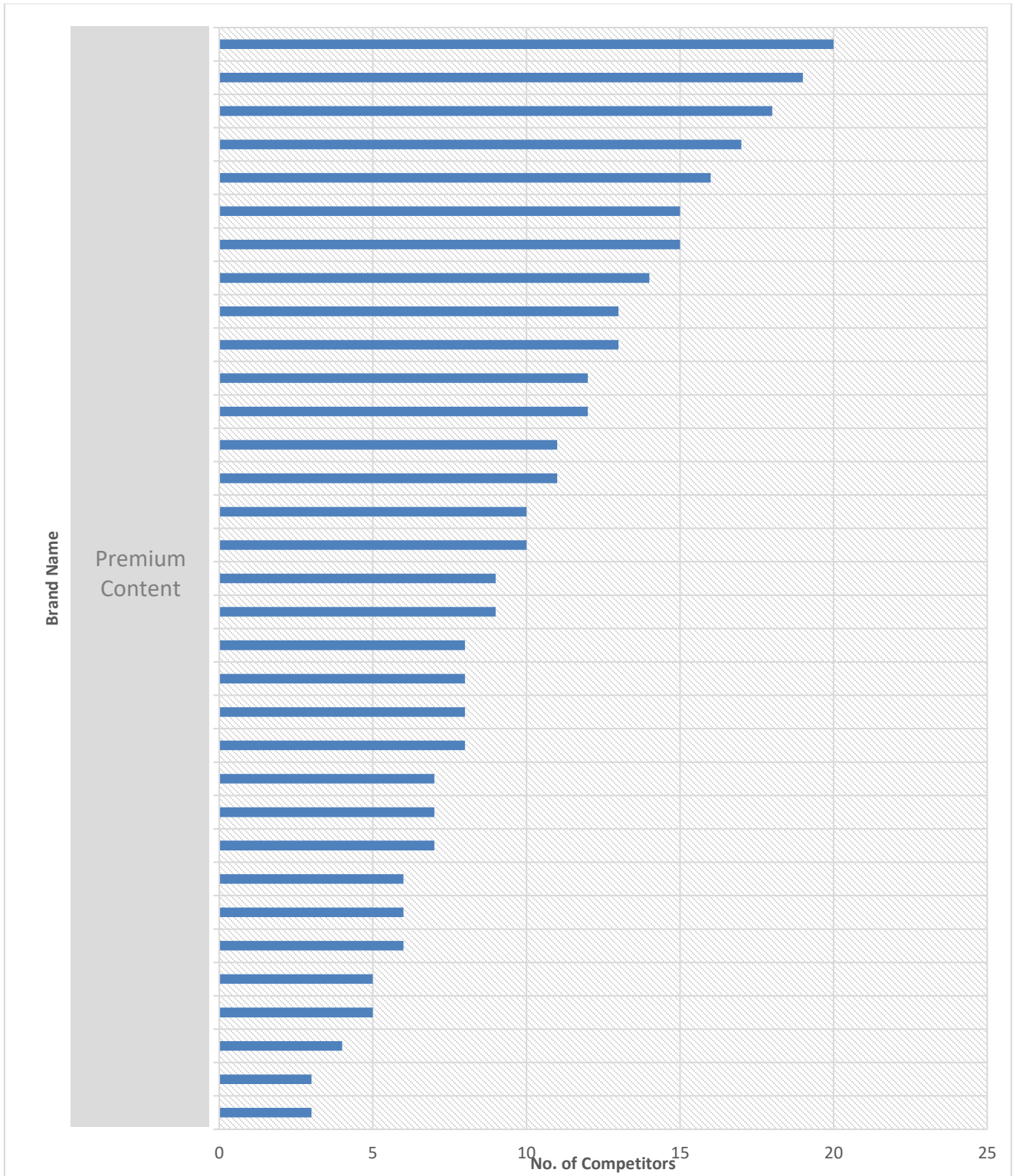
Chart 1
UNICHEM'S PRODUCT WISE MARKET SHARE



Note: Market share calculated based on 12 months sale ended in December 2023

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Chart 2
PRODUCT WISE COMPETITION LANDSCAPE



Note: No of competitors counted as of today



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Detailed Analyses



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**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 CY23 (IN USD MN)	% of Unichem US Sales	Unichem Market Share
1	203192	ALFUZOSIN HYDROCHLORIDE	UROXATRAL (TABLET)	UNICHEM	APOTEX, SUN PHARMA , AUROBINDO , INVAGEN				0.79	0.22%	38.10%
2	Premium Content										
3	Premium Content										
Total											

* Cos highlighted in red are Indian listed companies

Source:- GenUS, Research Delta Advisors

Note: Sales as per Medicaid Drug Rebate Program

Market share is Unichem's share of total generic sale of respective RLD



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**Table 2
COMMODITIZED PRODUCTS**

Sr No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other Facility for same ANDA	Sales CY23 (IN USD MN)	% of Unichem US Sales	Unichem Market Share
1	203245	AMLODIPINE BESYLATE	NORVASC (TABLET)	UNICHEM	17	(1) UNICHEM, Ghaziabad (2) CIPLA, Goa	36.57	10.16%	22.84%
2									
3									
4									
5									
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7									
8									
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16									
17									
18									

Premium Content



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Sr No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other Facility for same ANDA	Sales CY23 (IN USD MN)	% of Unichem US Sales	Unichem Market Share
19									
20									
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									
Total									

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

**Table 3
GOA FACILITY INSPECTION HISTORY**

Date	Classification
12-01-2020	Voluntary Action Indicated (VAI)
31-07-2019	Voluntary Action Indicated (VAI)
17-04-2015	Voluntary Action Indicated (VAI)