



Impact Analyses: Granules, Gagillapur

September 10, 2024

Granules India Ltd. announced its Gagillapur facility received 'Form 483' with six observations.

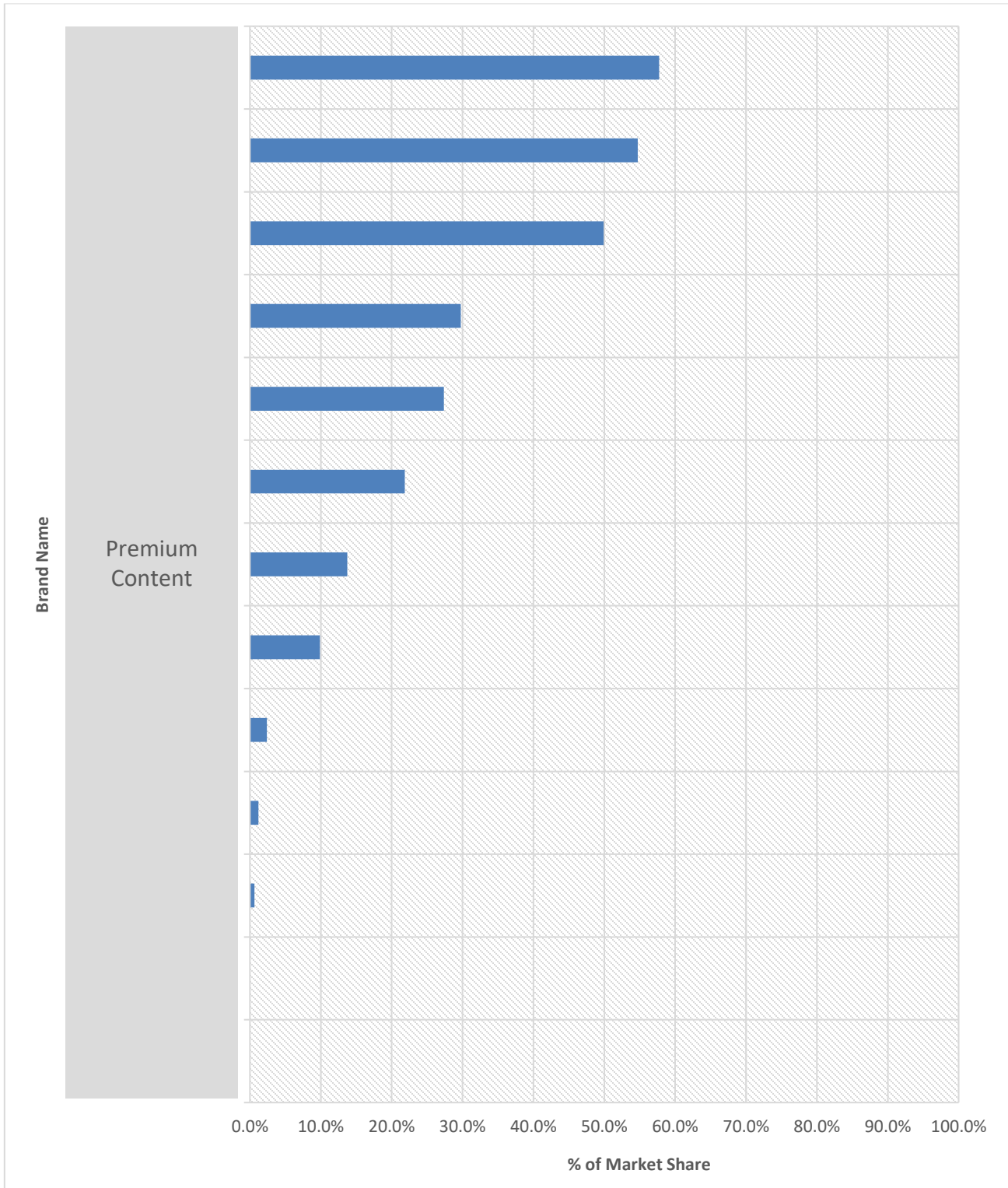
Granules India Ltd. in its press release announced that, its Gagillapur facility (Sy.No. 160/A, 161/E, 162, 174/A, Gagillapur Village, Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District, Telangana, India) received 'Form 483' with six observations. Granules India manufactures █ of the total 54 formulation products manufactured for the US market. This facility manufactures Oral Solids.

1. █ of the top 5 products manufactured by Granules for US market are manufactured in this facility.
2. █ and █ are among the top 5 products manufactured at this facility.
3. █ out of total █ products manufactured at this facility are high competition products.
4. █ of the products manufactured at this facility are backed by other facilities.
5. █ of the Products manufactured at this facility are partnered/contract manufactured products.

In terms of revenue impact, this facility contributes █ % (excluding sales of the products backed by other facilities) of total Granules' US sales (including partnered products). The facility has been under 'VAI' status since 2020. Given the █ contribution to overall sales, the worst-case impact on revenue (assuming an import alert) is likely to be █

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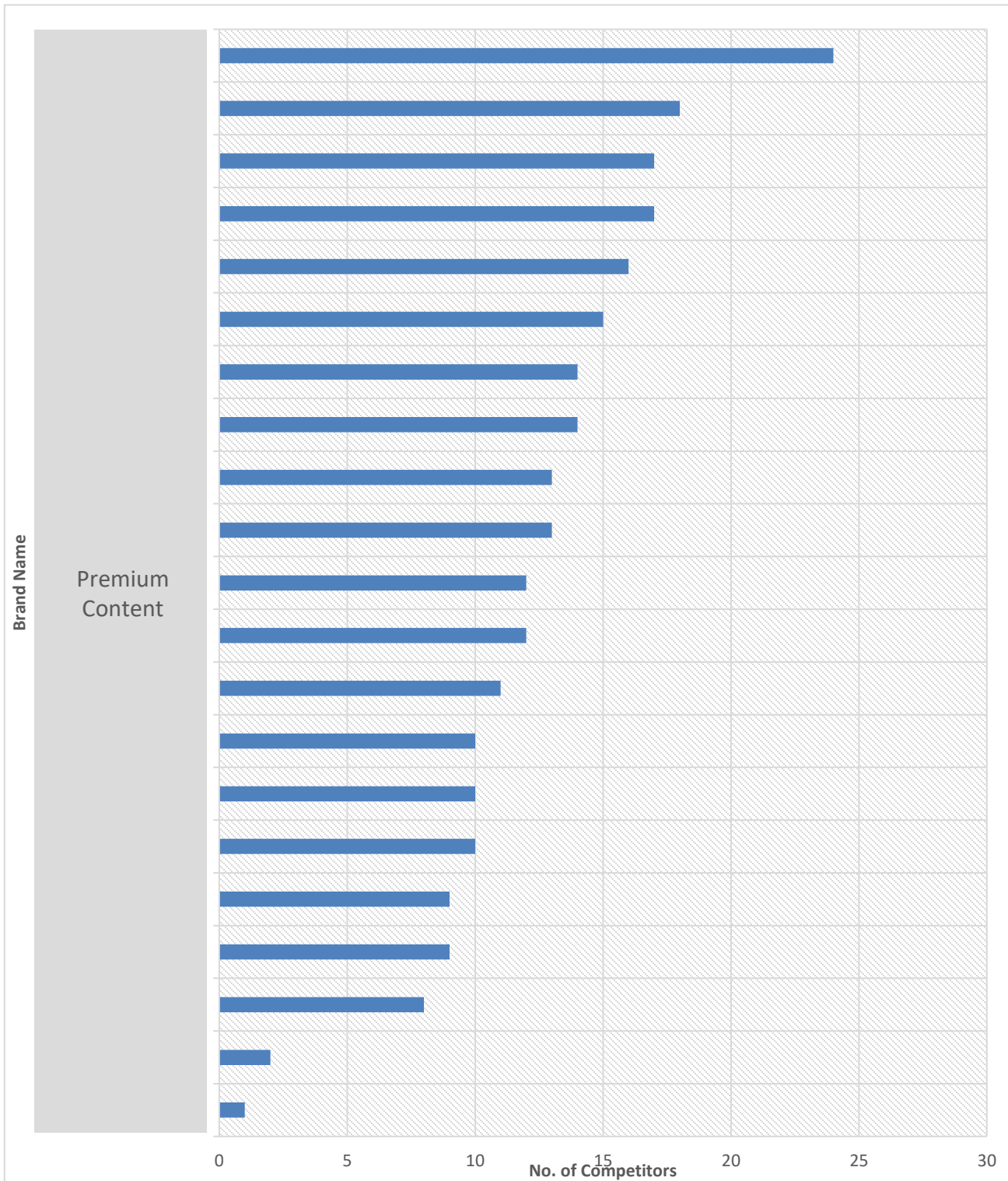
Chart 1
GRANULES' PRODUCT WISE MARKET SHARE



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 Granules US Sales	Granules Market Share
1	77226	BROMOCRIPTINE MESYLATE	PARLODEL (CAPSULE)	MYLAN	ZYDUS PHARMS			Naturally sourced ingredients	N/A	N/A	N/A
2	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 Granules' 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 Granules US Sales	Granules Market Share
1	90564	METFORMIN HYDROCHLORIDE	GLUCOPHAGE (TABLET)	GRANULES INDIA	17	(I) GRANULES, Virginia (II) GRANULES, Jeedimetla	81.52	25.53%	54.72%
2	<div style="background-color: #cccccc; padding: 50px;"> <h2>Premium Content</h2> </div>								
3									
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18									
19									
Total									

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

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Table 3
GAGILLAPUR FACILITY INSPECTION HISTORY

Date	Classification
14-02-2020	Voluntary Action Indicated (VAI)
23-03-2018	No Action Indicated (NAI)
14-10-2016	No Action Indicated (NAI)
13-03-2015	No Action Indicated (NAI)
13-09-2012	Voluntary Action Indicated (VAI)