



# Impact Analyses: Indoco, Goa Plant-II

July 31, 2024

## **Indoco announced its Goa Plant II & III received 'Form 483' with seven observations.**

Indoco Remedies in its press release announced that, its Goa Plant II & III (Goa Plant-II & III, L-32,33,34, Verna Industrial Area, Verna, Goa, India) received 'Form 483' with seven observations. This is 1 of the 2 USFDA approved facilities owned by the company. Indoco manufactures █ of the total 27 formulation products manufactured for the US market in this facility. This facility manufactures Oral Solids, Injectable and Ophthalmic products.

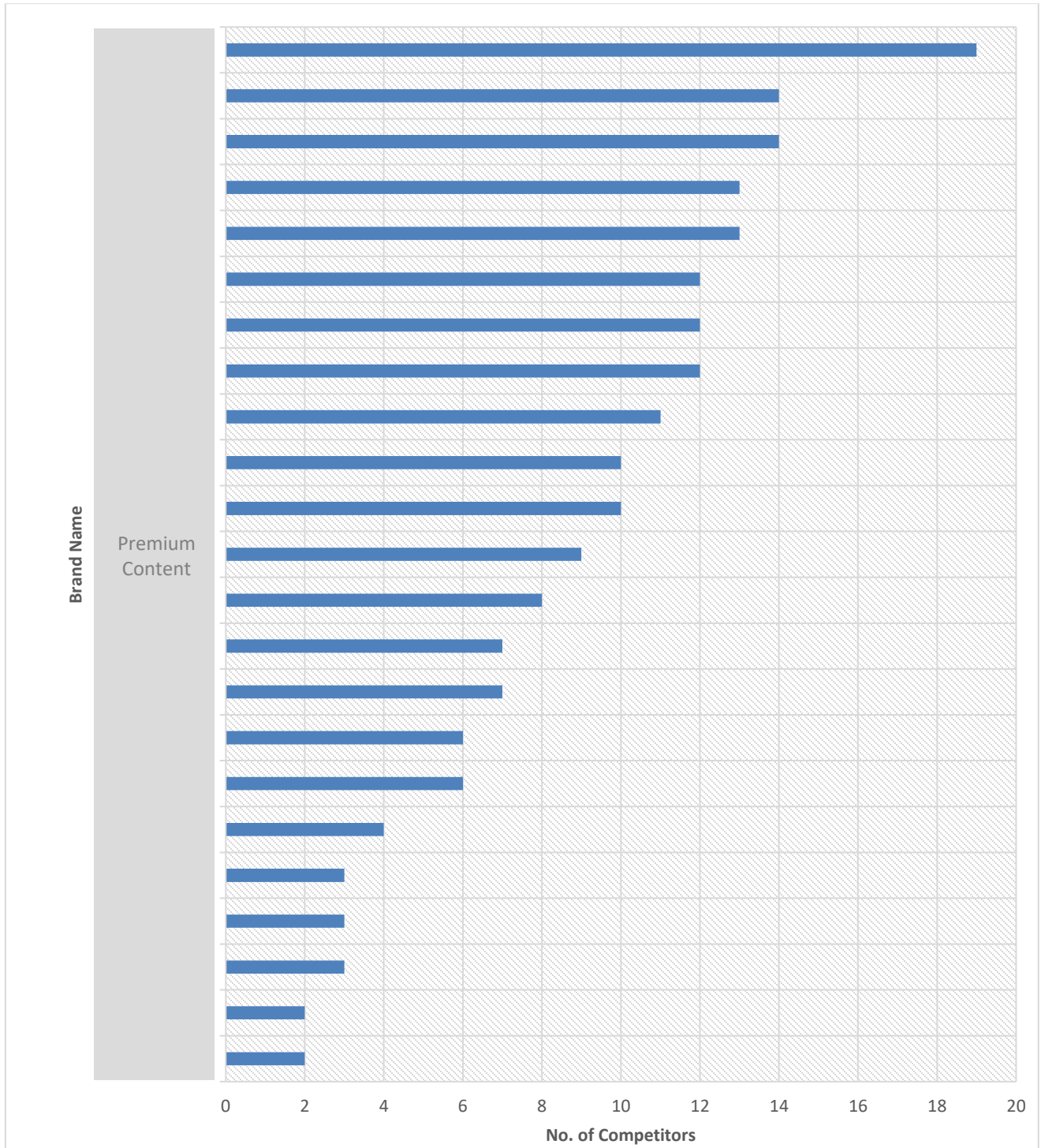
1. █ of the top 5 products manufactured by Indoco for US market are manufactured in this facility.
2. █ of the Products manufactured at this facility are partnered/contract manufactured products.
3. █ of the products manufactured at this facility are backed by other facilities.

In terms of revenue impact, this facility contributes █ (excluding sales of the products backed by other facilities) of total Indoco's US sales (including partnered products). The facility has been under 'OAI' status since 2023. Given the █ contribution to overall sales, the worst-case impact on revenue (assuming an import alert) is █.



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Chart 2  
PRODUCT WISE COMPETITION LANDSCAPE



Note: No of competitors counted as of today

# ***Detailed Analyses***



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**Table 1**  
**LOW COMPETITION PRODUCTS - CONTRACT MANUFACTURED**

Sr. No.	ANDA No.	Generic Name	Brand Name	ANDA Owner	Other Manufacturer for Same ANDA	Other Gx competitors	Other ANDA Developers	Sales CY23 (IN USD MN)	% of Indoco US Sales	Indoco Market Share
1	77700	LEVOFLOXACIN	QUIXIN (OPHTHALMIC)	RISING		SAPTALIS PHARMS, WATSON	None	N/A	N/A	N/A
2	Premium Content									
3										
4										
5										
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 Indoco's share of total generic sale of respective RLD



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**Table 2  
COMMODITIZED PRODUCTS - CONTRACT MANUFACTURED**

Sr No.	ANDA No.	Generic Name	Brand Name	ANDA Owner	Other Manufacturer for Same ANDA	Other Gx competitors	Sales CY23 (IN USD MN)	% of Indoco US Sales	Indoco Market Share
1	209860	TRANEXAMIC ACID	CYKLOKAPRON (INJECTION)	APOTEX		13	0.05	0%	0.34%
2	Premium Content								
3									
4									
5									
6									
<b>Total</b>							<b>1.87</b>	<b>3.42%</b>	

Source:- GenUS, Research Delta Advisors

Note: Sales as per Medicaid Drug Rebate Program

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



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**Table 3  
LOW COMPETITION PRODUCTS – OWN PRODUCTS**

Sr. No.	ANDA No.	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other ANDA Developers	Sales CY23 (IN USD MN)	% of Indoco US Sales	Indoco Market Share
1	209898	APIXABAN	ELIQUIS (TABLET)	INDOCO REMEDIES	ACCORD HLTHCARE, HETERO, <b>SUN PHARMA</b>	<b>CIPLA, BIOCON,</b> MSN LABS, SANOFI, <b>AJANTA PHARMA,</b> MICRO LABS, <b>DR REDDY'S, BLISS GVS PHARMA,</b> MYLAN, UMEDICA, AIZANT, DELEXCEL PHARMA, <b>ZYDUS CADILA,</b> ECRON ACUNOVA, SLAYBACK PHARMA, MACLEODS, BAROQUE PHARMA, JEEVAN SCIENTIFIC, <b>MANKIND PHARMA,</b> CENTAUR PHARMA, FTF PHARMA,	N/A	N/A	N/A
<b>Total</b>							<b>0.00</b>	<b>0.00</b>	

\* Cos highlighted in red are Indian listed companies  
 Source:- GenUS, Research Delta Advisors  
 Note: Sales as per Medicaid Drug Rebate Program  
 Market share is Indoco's share of total generic sale of respective RLD



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**Table 4  
COMMODITIZED PRODUCTS – OWN PRODUCTS**

Sr. No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Sales CY23 (IN USD MN)	% of Indoco US Sales	Indoco Market Share								
1	204467	ALLOPURINOL	ZYLOPRIM (TABLET)	INDOCO REMEDIES	(1)INDOCO REMEDIES, Unit-I (2)HERITAGE PHARMA, New Jersey	12	5.40	9.91%	24.00%							
2	Premium Content															
3																
5																
6																
7																
8																
9																
10																
11																
12																
Total																

Source:- GenUS, Research Delta Advisors

Note: Sales as per Medicaid Drug Rebate Program

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



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Table 3  
GOA FACILITY INSPECTION HISTORY

Date	Classification
28-02-2023	Official Action Indicated (OAI)
21-11-2018	Voluntary Action Indicated (VAI)
04-09-2016	Official Action Indicated (OAI)