

# Potential Drug Shortages in US

## Analyses of GMP Deviations since 2018

17<sup>th</sup> February, 2024

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## Executive Summary:

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**Regulatory Issues – A Prime Reason for Drug Shortages in US:** Drug Shortages is a major issue in the US leading to price increases of drugs under shortages. On an average, ~250 drugs remain under shortages in the US on any given day. As per the USFDA, non compliance to CGMP norms for manufacturing is one of the 3 main reasons for drug shortages. Post the USFDA inspection of any facility, it classifies facilities into OAI, VAI and NAI. Issuance of an OAI is the starting point of all CGMP non compliance issues that, when escalated, can result in a Warning Letter or an Import Alert that can ultimately disrupt drug supplies from that facility.

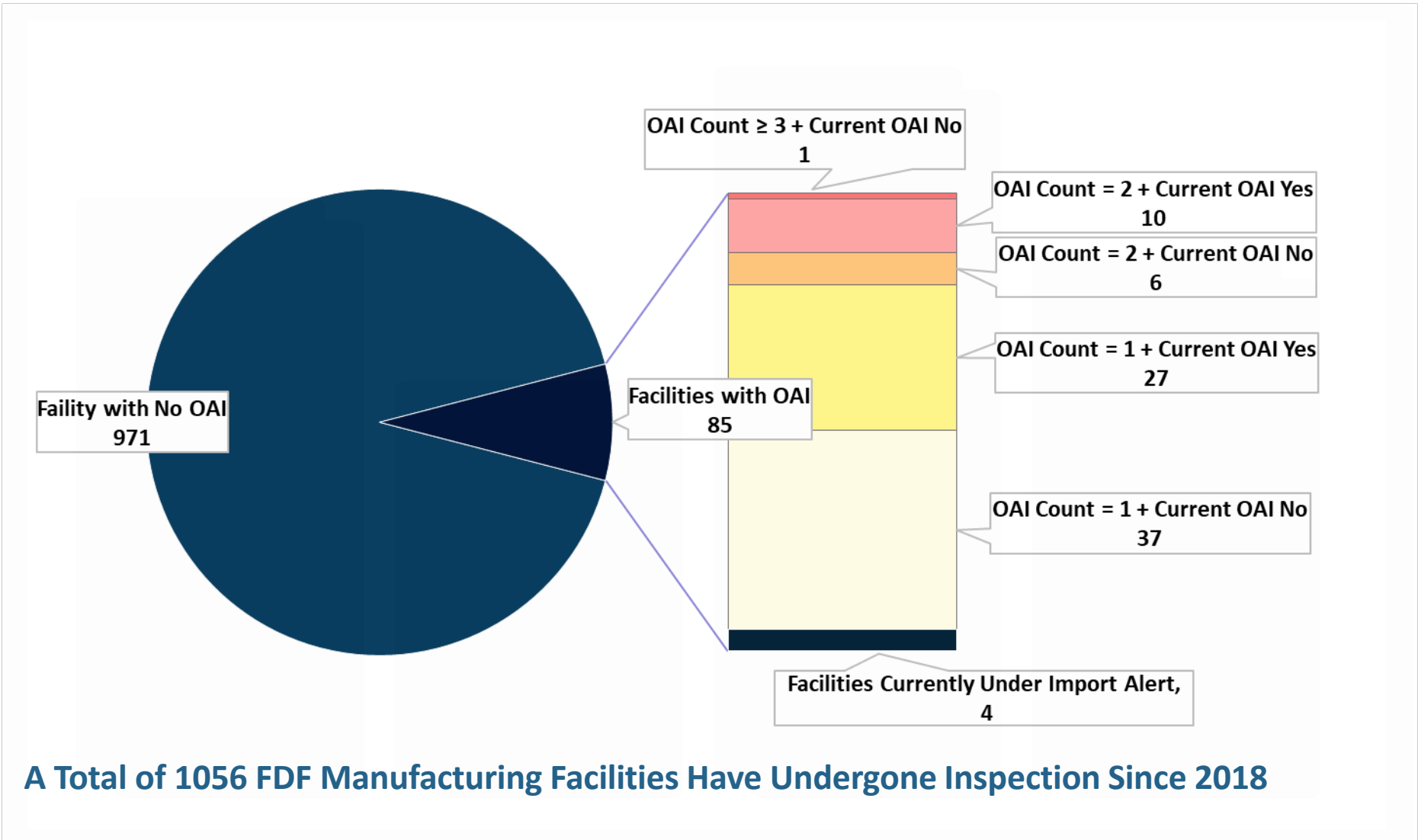
**Identifying Facilities Under the Risk – a First Step in Estimating Drug Shortages:** We undertook an exercise to study CGMP compliance issues of Generic Finished Dosage Facilities since 2018 and identified drugs with generic market share above 25%. These drugs are potentially exposed to shortages in the event of an Import Alert. This in turn can potentially lead to drug price increase.

**US and Indian Facilities Remain Exposed the Most:** Of the 12 facilities we identified as having products that can potentially come under shortages, 5 are from India, 6 from the US and 1 from China representing ~\$375 mn of sales from 26 generic drugs.

**Potential Shortages Offer Opportunities for Other Generics:** Any shortage drives the price of that generic up as key competition moves out. And in a fiercely competitive market, any price rise is an opportunity worth lapping up. However, the best product opportunity is not the product with highest sales, but is a function of sales, market share and the chances of the facility's GMP risk escalating.

**Top 10 Recommended Product Opportunities:** We offer an Opportunity Score derived from all the 3 factors to recommend the top 10 products to focus on as a generic manufacturer. The top 10 products reflect a combined sales of ~\$215 mn

# GMP Record of Facilities Inspected Since 2018



# Risk wise categorization of facilities

Risk Category	Facility with Total OAI Count + Current OAI Yes/No	No. of Facility with OAI	Removed Currently under Import alert facility	Risky Facility
Very High	OAI Count $\geq 3$ + Current OAI No	1	-	1
High	OAI Count = 2 + Current OAI Yes	12	2	10
Moderate	OAI Count = 2 + Current OAI No	6	-	6
Low	OAI Count = 1 + Current OAI Yes	29	2	27
Very Low	OAI Count = 1 + Current OAI No	37	-	(Very low risk facilities – not considered)
	<b>Total</b>	<b>85</b>		<b>44</b>

In this analysis, we categorized FDA drug manufacturing facilities into five risk levels based on their Official Action **Indicated (OAI) records and current compliance status**. Facilities with a higher count of OAI records since 2018 and ongoing compliance issues pose a greater risk of potential drug shortages.

To refine our prediction model, **4 Facilities (2 from High Risk and 2 from Low Risk) under an active Import Alert** have been removed, as the impact on future shortages has likely been absorbed by the market.

**37 Facilities in the Very Low risk category** have been excluded from the analysis, as their minimal compliance issues indicate a low likelihood of causing supply disruptions.

## 44 Facilities With Active Supplies Present a Meaningful Risk of Future Shortages

# Risk wise categorization of products

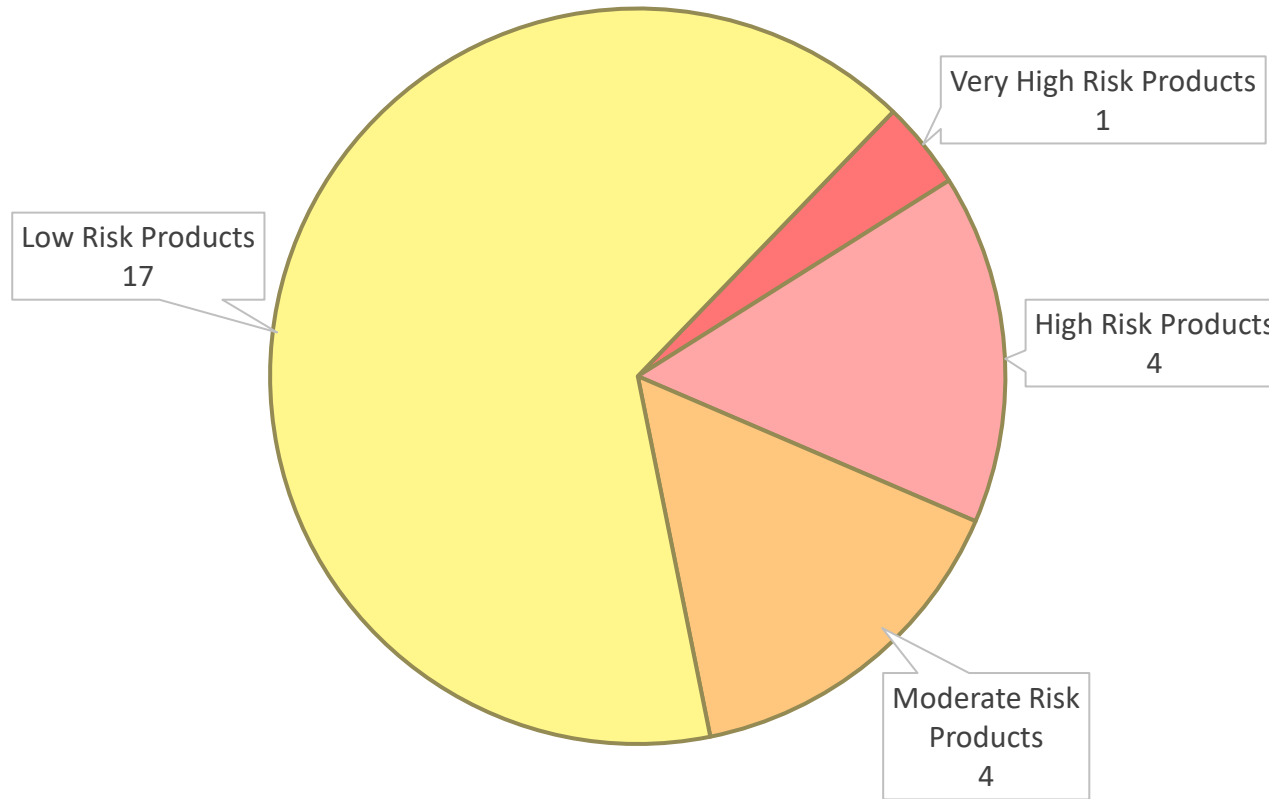
Risk Category	Facility with Total OAI Count + Current OAI Yes/No	Risky Facility Count	Risky Product Count
Very High	OAI Count $\geq 3$ + Current OAI No	1	10
High	OAI Count = 2 + Current OAI Yes	10	69
Moderate	OAI Count = 2 + Current OAI No	6	180
Low	OAI Count = 1 + Current OAI Yes	27	464
	<b>Risky Facilities that actively supply the market</b>	<b>44</b>	<b>723</b>

From the Above List, the following Products are Excluded

- **Low-revenue and low market share products** (sales below \$5M and 25% market share).
- **Products with backup manufacturing facilities**, ensuring supply continuity.

**Out of 44 Facilities and 723 Products, a Total of 12 Facilities and 26 Products are Shortlisted Based on Above Criteria**

# Risk wise categorization of No. of Products Exposed to Shortages



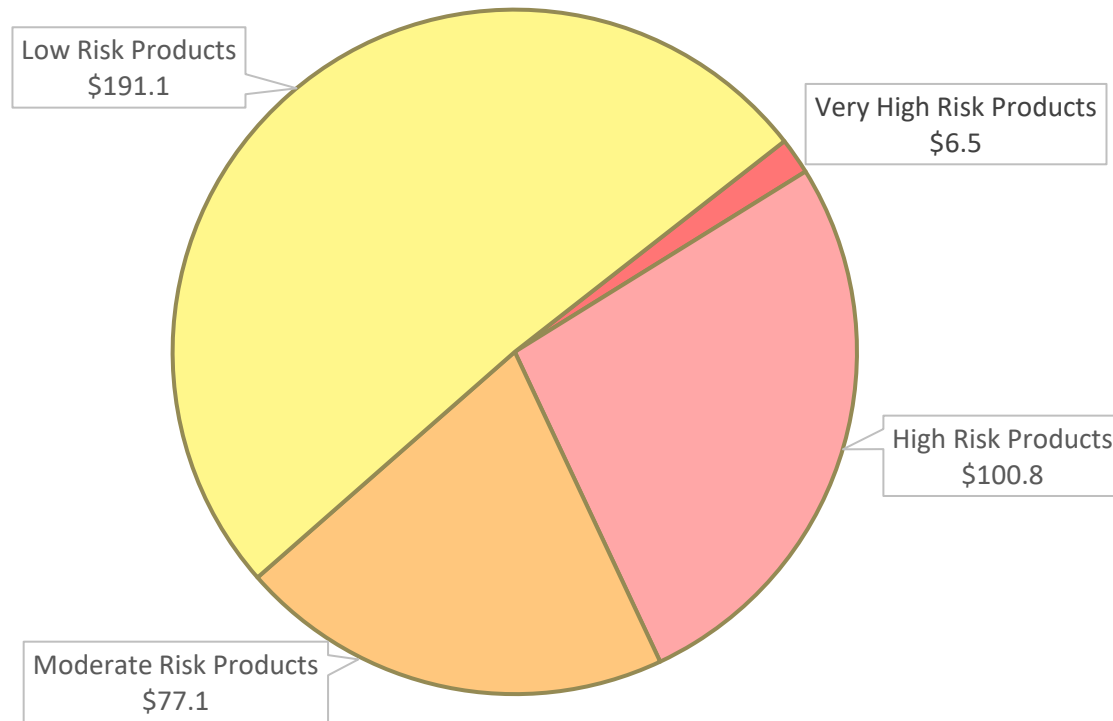
Source: GenUS Database, Research Delta Advisors

- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024  
2. Market share is the generic market share of respective RLD  
3. Products with sales <\$5mn p.a. are excluded  
4. Products backed up by another manufacturing facility are excluded

# Risk wise categorization of Product Sales Exposed to Shortages



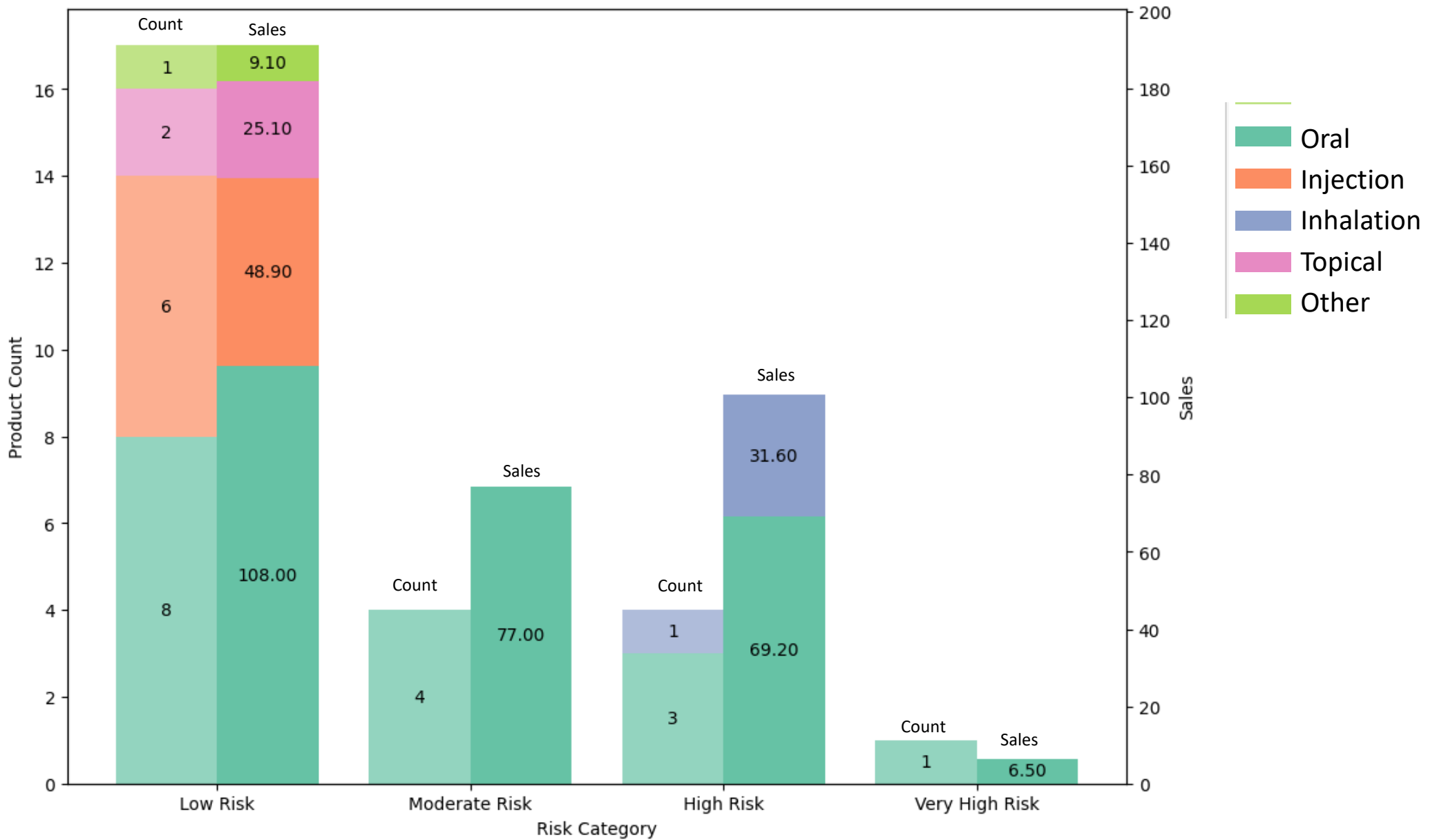
(in Million)



Source: GenUS Database, Research Delta Advisors

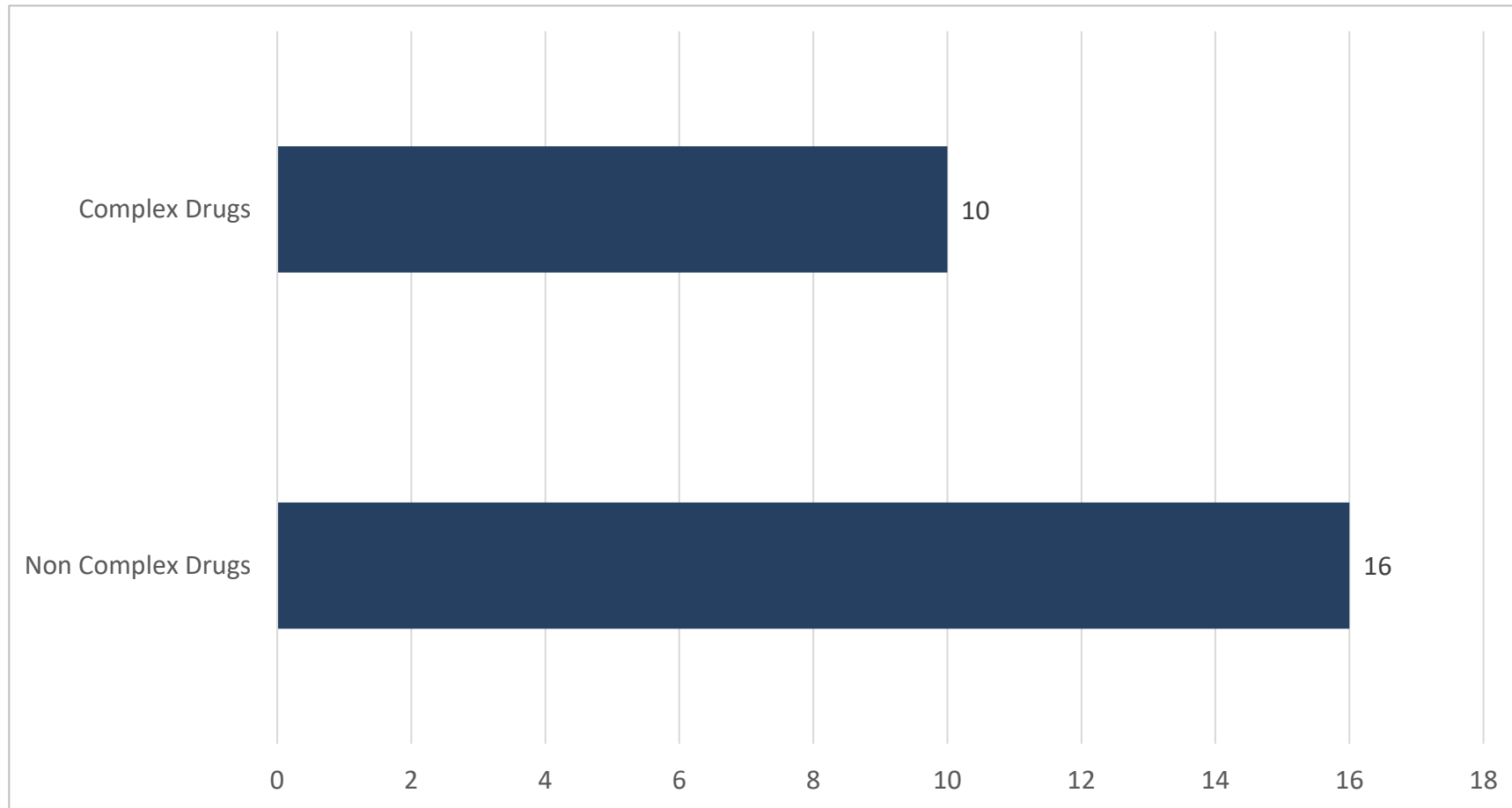
- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024  
2. Market share is the generic market share of respective RLD  
3. Products with sales <\$5mn p.a. are excluded  
4. Products backed up by another manufacturing facility are excluded

# Products Exposed to Shortages – Route of Administration





# Products Exposed to Shortages – Complex vs Non Complex



Source: GenUS Database, Research Delta Advisors

- Note:
1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024
  2. Market share is the generic market share of respective RLD
  3. Products with sales <\$5mn p.a. are excluded
  4. Products backed up by another manufacturing facility are excluded

# List of Products Exposed to Potential Shortages.....Category 1



## Category 1: Products with **Very High Risk** (Facility with OAI Count $\geq 3$ )

Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share
1	Premium Content								

Source: GenUS Database, Research Delta Advisors

- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024  
 2. Market share is the generic market share of respective RLD  
 3. Products with sales <\$5mn p.a. are excluded  
 4. Products backed up by another manufacturing facility are excluded

# List of Products Exposed to Potential Shortages.....Category 2



## Category 2: Products with **High Risk** (Facility with OAI Count = 2 & currently under OAI)

Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share
1	Premium Content								
2									
3									
4									

Source: GenUS Database, Research Delta Advisors

- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024  
 2. Market share is the generic market share of respective RLD  
 3. Products with sales <\$5mn p.a. are excluded  
 4. Products backed up by another manufacturing facility are excluded



# List of Products Exposed to Potential Shortages.....Category 3

## Category 3: Products with **Moderate Risk** (Facility with OAI Count = 2 & currently NOT under OAI)

Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share
1	Premium Content								
2									
3									
4									

Source: GenUS Database, Research Delta Advisors

- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024
- 2. Market share is the generic market share of respective RLD
- 3. Products with sales <\$5mn p.a. are excluded
- 4. Products backed up by another manufacturing facility are excluded



# List of Products Exposed to Potential Shortages.....Category 4

## Category 4: Products with Low Risk (Facility with OAI Count = 1 & currently under OAI)

Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share
1	Premium Content								
2									
3									
4									
5									
6									
7									

Source: GenUS Database, Research Delta Advisors

- Note:
- 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024
  - 2. Market share is the generic market share of respective RLD
  - 3. Products with sales <\$5mn p.a. are excluded
  - 4. Products backed up by another manufacturing facility are excluded



# List of Products Exposed to Potential Shortages...Category 4 (Contd)

## Category 4: Products with **Low Risk** (Facility with OAI Count = 1 & currently under OAI)

Sr. No	Drug Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share
8	Premium Content								
9									
10									
11									
12									
13									

Source: GenUS Database, Research Delta Advisors

- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024
- 2. Market share is the generic market share of respective RLD
- 3. Products with sales <\$5mn p.a. are excluded
- 4. Products backed up by another manufacturing facility are excluded

# List of Products Exposed to Potential Shortages...Category 4 (Contd)



## Category 4: Products with Low Risk (Facility with OAI Count = 1 & currently under OAI)

Sr. No	Drug Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share
14	Premium Content								
15									
16									
17									

Source: GenUS Database, Research Delta Advisors

- Note: 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024  
 2. Market share is the generic market share of respective RLD  
 3. Products with sales <\$5mn p.a. are excluded  
 4. Products backed up by another manufacturing facility are excluded

# Potential Shortages – Top 10 Product Opportunities

**Potential Shortages are Potential Business Opportunities:** Generic manufacturers can target products with potential shortages to exploit the opportunity that may be created.

Recommended products to target are a function of sales, risk categorization and market share.

**Opportunity Score:** We have developed an Opportunity Score based on product sales, facility risk category and generic market share.

Sr. No	Drug Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share	Opportunity Score
1	Premium Content									
2										
3										
4										



# Top 10 Product Opportunities Based on Opportunity Score (Contd)

Sr. No	Drug Name	Strength	Dosage Form	Complexity	ANDA No	Generic Co.	Manufacturer	Anda Total Sales (M)	Anda Market Share	Opportunity Score
5	Premium Content									
6										
7										
8										
9										
10										

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# ANNEXURES

# Annexure 1

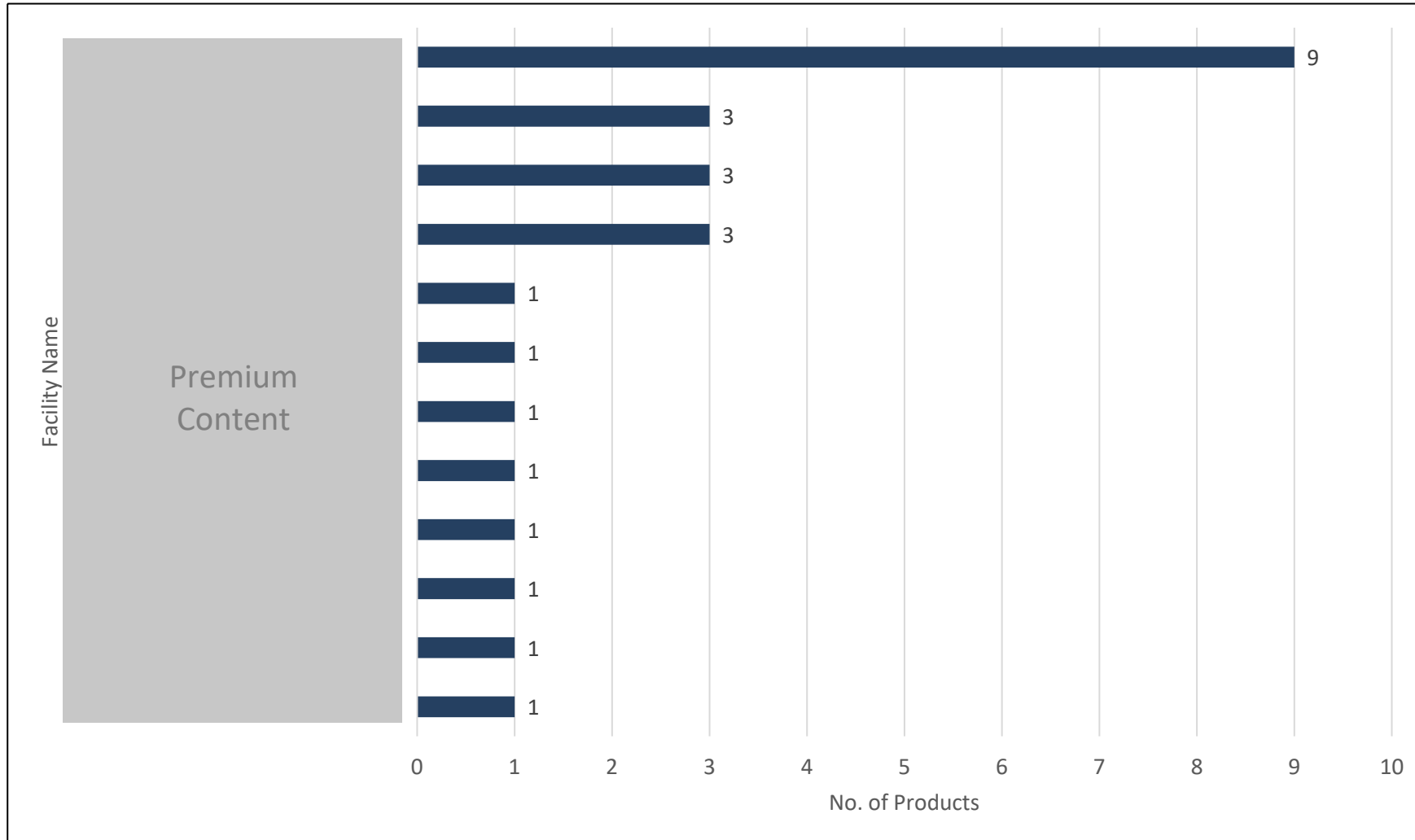
## Key Facilities with Products Exposed to Potential Shortages

Sr No	Firm Name	Address	OAI Count	Inspection Count	Last Inspection Status
1	Premium Content				
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

# Annexure 2



## Co. wise Exposure to Potential Shortages (Product Count)

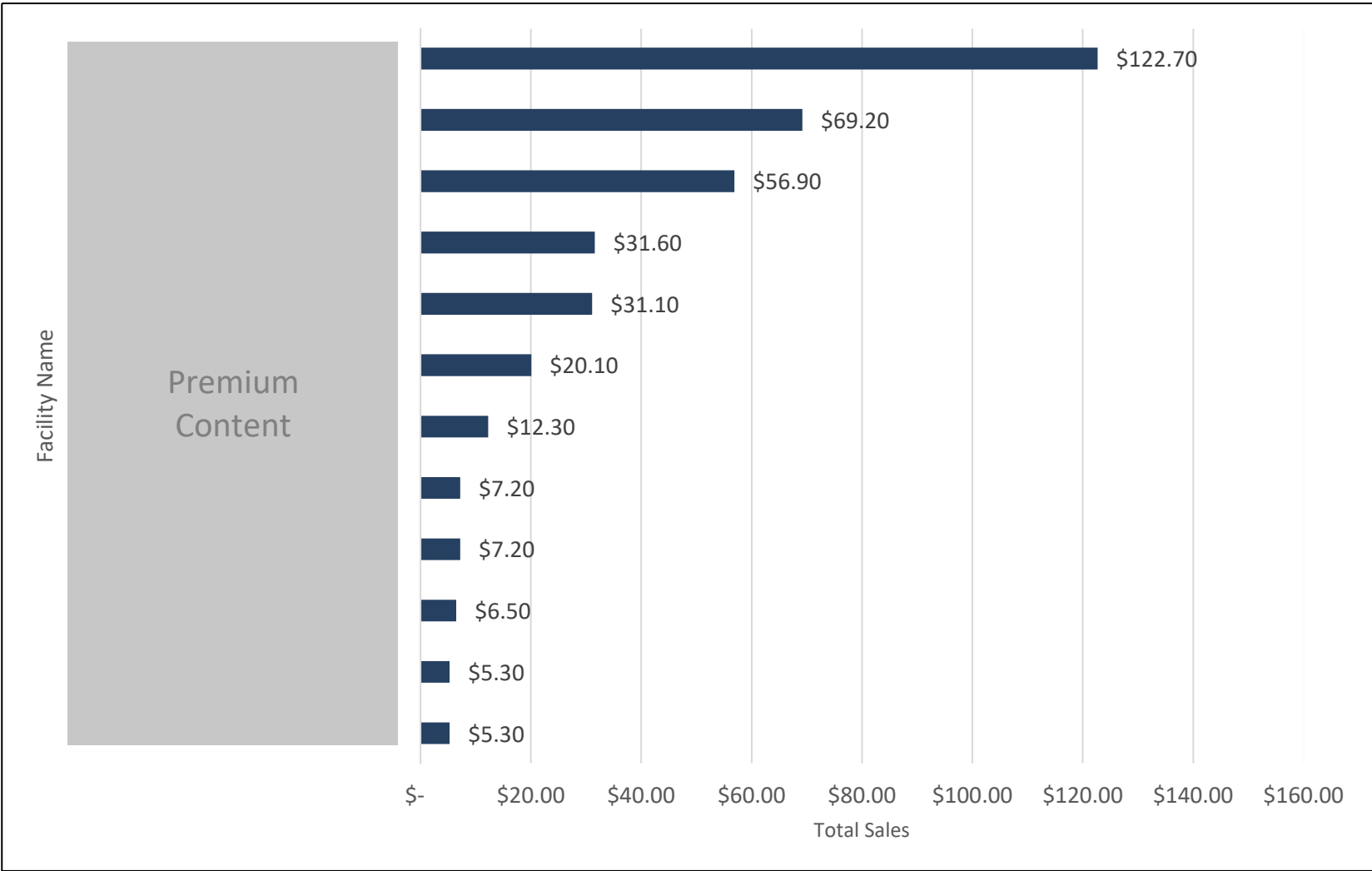


Source: GenUS Database, Research Delta Advisors

- Note:
- 1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024
  - 2. Market share is the generic market share of respective RLD
  - 3. Products with sales <\$5mn p.a. are excluded
  - 4. Products backed up by another manufacturing facility are excluded

# Annexure 3

## Co. wise Exposure to Potential Shortages (Product Sales)



Source: GenUS Database, Research Delta Advisors

- Note:
1. Sales as per Medicaid Drug Rebate Program for 12 months ending June 2024
  2. Market share is the generic market share of respective RLD
  3. Products with sales <\$5mn p.a. are excluded
  4. Products backed up by another manufacturing facility are excluded

# Annexure 4



## List of Facilities with OAI>1 since 2018

Sr No	Firm Name	Address	OAI Count	Inspection Count	Last Inspection Status
1	Jubilant Generics Limited	Bhagwanpur, Roorkee, India	Premium Content		VAI 02-02-2024
2	Nephron Sc Inc	4500 12th Street Ext, West Columbia, SC, 29172-3025, United States			OAI 09-02-2024
3	Lupin Limited	Unit 1, 198 - 202 New Ind Area No 2, Mandideep, India			OAI 23-11-2022
4	Madhu Instruments Private Limited (Having Open Import Alert)	A - 260 Okhla Industrial Area Phase 1'St Road, New Delhi, India			OAI 21-10-2022
5	Milbar Laboratories, Inc.	20 Commerce St, East Haven, CT, 06512-4145, United States			OAI 27-09-2022
6	Altaire Pharmaceuticals, Inc.	311 W Ln, Aquebogue, NY, 11931, United States			OAI 11-02-2022
7	Advanced Pharmaceutical Technology Inc.	132 S Central Ave, Elmsford, NY, 10523-3509, United States			OAI 01-08-2024
8	Cetylite Industries, Inc.	9051 River Rd, Pennsauken, NJ, 08110-3203, United States			OAI 02-03-2023
9	KVK Tech, Inc.	110 Terry Dr, Newtown, PA, 18940-3427, United States			OAI 08-07-2022
10	ALK-Abello, Inc.	10 Farmington Valley Dr Ste 106, Plainville, CT, 06062-1182, United States			OAI 21-10-2022
11	Panacea Biotec Pharma Limited	Malpur, Baddi, Pharma Block, Solan, India			OAI 12-10-2023
12	Sun Pharmaceutical Industries Ltd. (Having Open Import alert)	Halol - Baroda Highway, Halol, India			OAI 09-05-2022
13	Sovereign Pharmaceuticals, LLC	7590 Sand St, Fort Worth, TX, 76118-6977, United States			OAI 02-08-2023
14	Sanitor Corporation	8400 Cerritos Ave, Stanton, CA, 90680-2504, United States			VAI 10-05-2024
15	Fresenius Kabi USA LLC	2020 N Ruby St, Melrose Park, IL, 60160-1112, United States			VAI 24-08-2023
16	The Tender Corporation	944 Industrial Park Rd, Littleton, NH, 03561-3956, United States			VAI 26-04-2023

# Annexure 4



Sr No	Firm Name	Address	OAI Count	Inspection Count	Last Inspection Status
17	Acella Pharmaceuticals, LLC	1880 Mcfarland Pkwy Ste 110, Alpharetta, GA, 30005-1795, United States	Premium Content		VAI 10-02-2023
18	Somerset Therapeutics Limited	54/1 Boodihal Village, Bengaluru, India			VAI 27-10-2023
19	Cipla Limited	1 2 3 L - 147 A L - 138 L - 150 S - 116 To L - 147, I D C Verna Industrial Road; L147 To S - 112, Vasco Da Gama, India			VAI 21-06-2024
20	Massco Dental	1506 N 2nd St, Rogers, AR, 72756-2418, United States			OAI 01-08-2024
21	Accra-Pac, Inc.	1919 Superior St, Elkhart, IN, 46516-4707, United States			OAI 26-07-2024
22	Glenmark Pharmaceuticals Inc USA	4147 Goldmine Rd, Monroe, NC, 28110-7759, United States			OAI 09-07-2024
23	Fenwal International, Inc.	Rd 357, Km 0.8, Maricao, PR, 00606, United States			OAI 03-05-2024
24	Sombra Cosmetics, Inc	5951 Office Blvd Ne, Albuquerque, NM, 87109-5822, United States			OAI 09-02-2024
25	Pharma Nobis LLC	7400 Alumax Rd, Texarkana, TX, 75501-0282, United States			OAI 02-02-2024
26	Baxter Healthcare Corporation	25212 W Il Route 120, Round Lake, IL, 60073-9799, United States			OAI 16-01-2024
27	Porton Biopharma Limited	Manor Farm, Salisbury, United Kingdom			OAI 15-12-2023
28	Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Huanghe Road Site)	Dev. Zone, Economic & Technological; 38 Huanghe Avenue, Lianyungang, China			OAI 17-11-2023
29	Windlas Healthcare Private Limited (Having Open Import alert)	Plot No 183 & 192 Mohabewala Industrial, Dehradun, India			OAI 17-02-2023
30	Emcure Pharmaceuticals Limited (Having Open Import alert)	Plot No P2, Midc Hinjawadi; Itbt Park, Pune, India			OAI 10-02-2023
31	Baxter Healthcare Corporation	65 Pitts Station Rd, Marion, NC, 28752-7925, United States	OAI 08-02-2023		
32	Vitae Enim Vitae Scientific, Inc.	3030 Bunker Hill St Ste 203, San Diego, CA, 92109-5754, United States	OAI 27-01-2023		
33	Universal Packaging Systems, Inc. dba PakLab	14570 Monte Vista Ave, Chino, CA, 91710-5743, United States	OAI 02-12-2022		
34	Iso-TEX Diagnostics, Inc.	1511 County Road 129, Alvin, TX, 77511-1466, United States	OAI 17-11-2022		

# Annexure 4



Sr No	Firm Name	Address	OAI Count	Inspection Count	Last Inspection Status
35	Pillar5 Pharma Inc.	365 Madawaska Blvd, Arnprior, Canada	Premium Content		OAI 18-10-2022
36	USV Private Limited	H - 13 16 16a 17 18 Atiyawad Dabhel Daman Road, Daman, India			OAI 02-09-2022
37	Centaur Pharmaceuticals Private Ltd.	Plot 4, Hinjewadi, Phase-II, International Biotech Park, Pune, India			OAI 02-09-2022
38	Glenmark Pharmaceuticals Limited	Village Kishanpura, Baddi Nalagarh Road, Baddi, Solan, India			OAI 12-08-2022
39	Glenmark Pharmaceuticals Limited	Plot No S - 7, Colvale Industrial Estate, Colvale, India			OAI 22-06-2022
40	Recipharm Monts	Site de Monts Sud, 18 rue de Montbazon, Monts, France			OAI 20-05-2022
41	Cipla Limited	Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic Zone, Pithampur, District Dhar, India			OAI 19-05-2022
42	Baxter Pharmaceuticals India Pvt Ltd	Village Vasana Chacharwadi, Taluka Sanand, Ahmedabad, India			OAI 07-12-2021
43	Genzyme Corporation	8, 31,45,49,51,55,68,74,76,80 New York Ave., Framingham, MA, 01701-8861, United States			OAI 24-09-2021
44	Sun Pharmaceutical Industries Limited	Unit 1 Plot A-41, Sez Industrial Area, Phase Viii A, Mohali, India			OAI 22-09-2021
45	Eugia Pharma Specialities Limited	34 - 48 Plot No 4, Unit Iii; Ida, Pashamylaram, India			OAI 21-05-2021
46	Aurolife Pharma, LLC	2400 US Highway 130, Dayton, NJ, 08810-1519, United States			OAI 13-03-2020
47	EUGIA Pharma Specialities Limited	Unit - 2, A - 1128 & B - 1127 Bhiwadi, Riico Industrial Area, India			OAI 30-08-2019
48	Intas Pharmaceuticals Limited	Plot No. 5 To 14, Pharmez, Near Village Matoda, Sarkhej-Bavla National Highway No. 8-A, Taluka, Sanand, Ahmedabad, India	OAI 20-02-2019		



# Annexure 5

## Products Manufacturing Backed up by Facility Without any OAI (Excluded in our study)

Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA	Generic Co.	Firm Name	Anda Total Sales (M)	Anda Market Share
1	Premium Content								
2									
3									
4									
5									
6									
7									
8									
9									

# Annexure 5 (Contd)



Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA	Generic Co.	Firm Name	Anda Total Sales (M)	Anda Market Share
10	Premium Content								
11									
12									
13									
14									
15									
16									

# Annexure 5 (Contd)

Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA	Generic Co.	Firm Name	Anda Total Sales (M)	Anda Market Share
17	Premium Content								
18									
19									
20									
21									
22									
23									
24									

# Annexure 5 (Contd)



Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA	Generic Co.	Firm Name	Anda Total Sales (M)	Anda Market Share
25	Premium Content								
26									
27									
28									
29									
30									

# Annexure 5 (Contd)



Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA	Generic Co.	Firm Name	Anda Total Sales (M)	Anda Market Share
31	Premium Content								
32									
33									
34									
35									
36									
37									

# Annexure 5 (Contd)



Sr. No	Generic Name	Strength	Dosage Form	Complexity	ANDA	Generic Co.	Firm Name	Anda Total Sales (M)	Anda Market Share
38	Premium Content								
39									
40									
41									
42									
43									
44									
45									