

# **IMPACT ANALYSIS: KVK TECH, NEWTOWN (PA), USA**

---

30<sup>th</sup> MAY, 2025

---



30<sup>th</sup> May, 2025

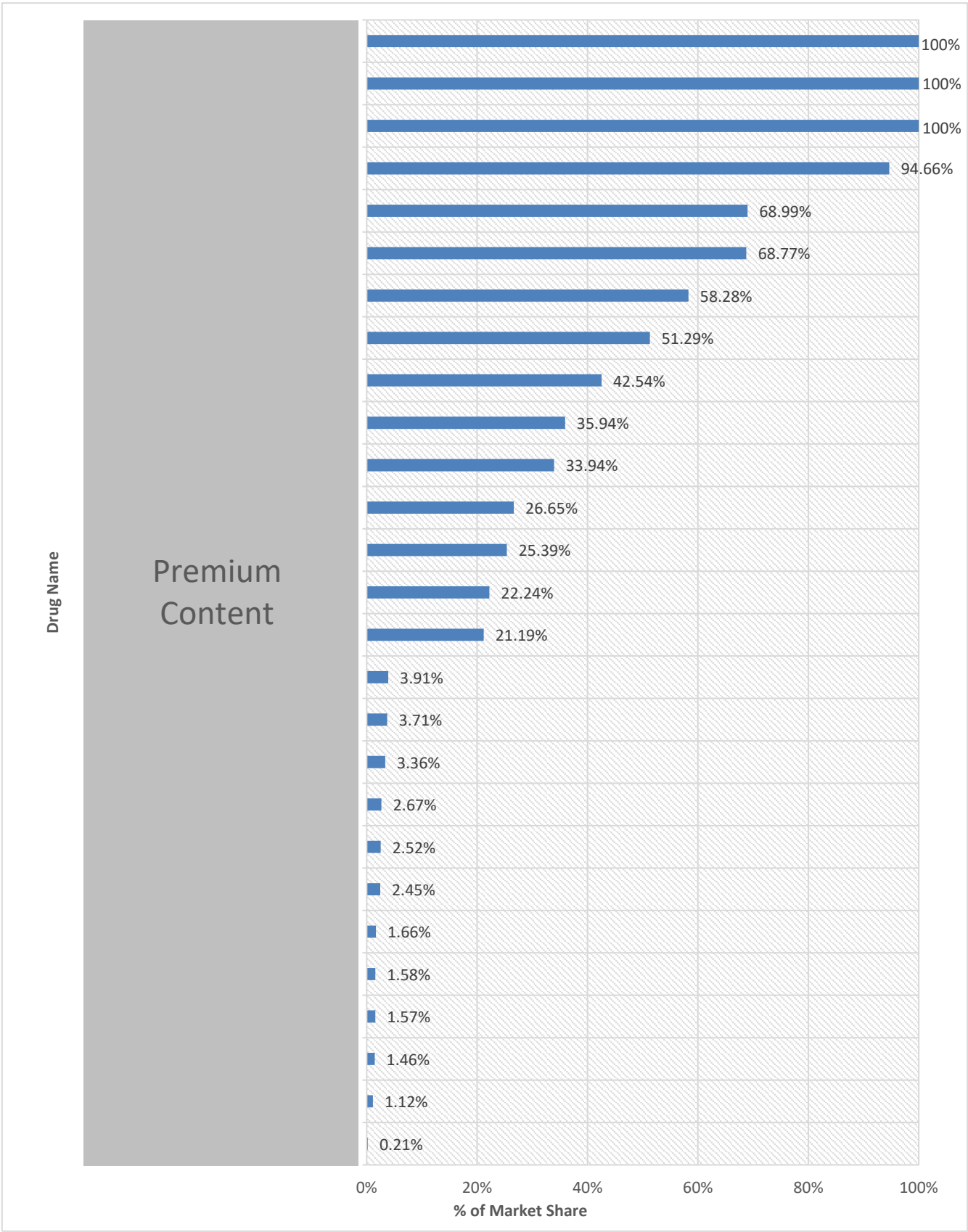
**KVK-TECH, INC. received an OAI (Official Action Indicated) classification from a USFDA**

**KVK-TECH, INC.** has received an '**Official Action Indicated (OAI)**' classification from the USFDA for its facility located at **110 Terry Drive, Newtown, Pennsylvania 18940, USA** following an inspection completed on **April 13, 2025**.

This Newtown facility is KVK's **manufacturing site** for US generics and is involved in the production of **oral solids and liquids**, with a focus on **controlled substances products**.

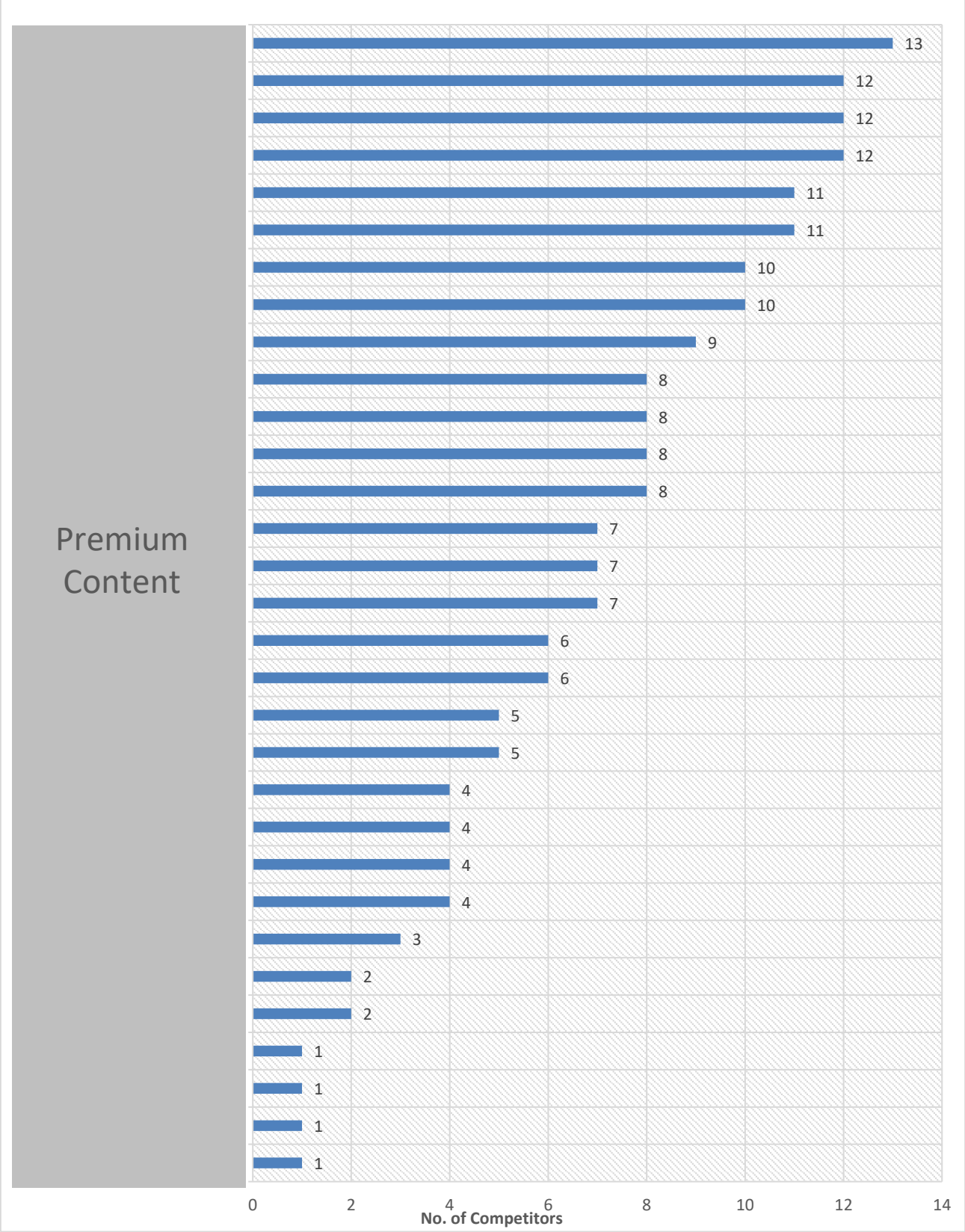
1. **Majority of KVK's portfolio consists of controlled substances**, which heightens regulatory scrutiny.
2. **Almost all the products are solely dependent** on the Newtown facility, **with no backup sites listed**.
3. [REDACTED] are among the top 3 products manufactured at this facility having sales more than [REDACTED] owned by [REDACTED].
4. [REDACTED] is a key product manufactured at this facility owned by KVK Tech having [REDACTED] in its therapeutic category.
5. 26 of the 38 products manufactured at this facility are contract manufactured products.

CHART 1: KVK TECH PRODUCT WISE MARKET SHARE



Note: Market share calculated based on 12 months sale ended in Q4-2024

CHART 2: PRODUCT WISE COMPETITION LANDSCAPE



Note: No of competitors counted as of today

## ***Detailed Analyses***

# Impact Analyses: KVK Tech, Newtown



**TABLE 1: LOW COMPETITION PRODUCTS**

Sr. No.	ApplNo	Generic Name	Brand Name	ANDA/NDA Owner	Other Gx competitors	Other ANDA Developers	Other Facility for same ANDA	Complexity	Sales CY24 (IN USD MN)	KVK Market Share
1	207488	METHYLPHENIDATE HCL	RITALIN-SR (Tablet ER)	ABHAI INC	SPECGX, GRANULES, ALKEM LABS	-	-	Controlled Substances	4.10	51.29%
2	Premium Content									
3										
4										
5										
6										
7										
8										

Source: - GenUS, Research Delta Advisors  
Note: Sales as per Medicaid Drug Rebate Program  
Market share is KVK Tech’s share of total generic sale of respective RLD  
*\*N208653 is an NDA Product*

# Impact Analyses: KVK Tech, Newtown



TABLE 2: COMMODITIZED PRODUCTS

Sr No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other Facility for same ANDA	Sales CY24 (IN USD MN)	KVK Tech Market Share
1	91393	OXYCODONE HCL	ROXICODONE (Tablet)	AVANTHI INC	10	-	30.53	25.39%
2								
3								
4								
5								
6								
7								
8								
9								
10								
11	(							
12								
13								
14								
15	(							
16								
17	(							
18								
19								
20								
21								
22								
23								
24								
25								

# Impact Analyses: KVK Tech, Newtown



TABLE 2: COMMODITIZED PRODUCTS (CONTINUED)

Sr No.	ANDA ApplNo	Generic Name	Brand Name	ANDA Owner	Other Gx competitors	Other Facility for same ANDA	Sales CY24 (IN USD MN)	KVK Tech Market Share
26		Premium Content						
27								
28								
29								
30								

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



**TABLE 3: KVK NEWTOWN FACILITY INSPECTION HISTORY**

Date	Classification
14-03-2025	Official Action Indicated (OAI)
08-07-2022	Official Action Indicated (OAI)
16-04-2019	Official Action Indicated (OAI)
27-06-2017	Voluntary Action Indicated (VAI)
11-12-2014	Voluntary Action Indicated (VAI)

**Regulatory Risk:** HIGH – OAI classification may lead to enforcement actions (e.g., Warning Letter, Import Alert)