

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR AUGUST 2025



LOW COMPETITION APPROVALS



31ST JULY–06TH AUG, 2025

Final Approvals

<i>Sr. No</i>	<i>Brand Name</i>	<i>Generic Name</i>	<i>Para IV Filers Yet To Be Approved</i>	<i>Approved Company Name</i>	<i>No. Of Final Approvals</i>	<i>Other ANDA Developers¹</i>
1.	Arazlo 0.045% Lotion, Topical	Tazarotene	PREMIUM CONTENT	Padagis	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

There are no Low Competition Tentative Approvals this week.

¹ Other ANDA Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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LOW COMPETITION APPROVALS



07TH AUG – 13TH AUG, 2025

Final Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers Yet To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developers ²
1.	Bridion Eq 200mg Base/2ml (Eq 100mg Base/ml) Solution; Intravenous	Sugammadex Sodium	PREMIUM CONTENT	Fisiopharma	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Ascor 25,000mg/50ml (500mg/ml) Solution; Intravenous	Ascorbic Acid	PREMIUM CONTENT	Fresenius Kabi	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Ketalar Eq 10mg Base/ML Injectable; Injection	Ketamine Hydrochloride	PREMIUM CONTENT	Pharmather	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Vfend 200mg/5ml; Suspension, Oral	Voriconazole	PREMIUM CONTENT	Hetero Labs	4 th	PREMIUM CONTENT

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	PREMIUM CONTENTS					
5.	Prilosec Otc Eq 20mg Base Tablet, Delayed Release; Oral	Omeprazole Magnesium	PREMIUM CONTENT	Marksans Pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Venofer Eq 50mg Iron/2.5ml (Eq 20mg Iron/ml) Eq 100mg Iron/5ml (Eq 20mg Iron/ml) Eq 200mg Iron/10ml (Eq 20mg Iron/ml) Injectable; Intravenous	Iron Sucrose	PREMIUM CONTENT	Intl Medication Sys, Mylan Labs and Sandoz	1 st , 2 nd , 3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Olumiant 1mg and 2mg Tablet	Baricitinib	PREMIUM CONTENT	MSN Labs	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
8.	Olumiant 4 mg Tablet	Baricitinib	PREMIUM CONTENT	MSN Labs	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
9.	Sodium Acetate 100meq/50ml (2meq/ml)	Sodium Acetate	PREMIUM CONTENT	Amneal	3 rd	PREMIUM CONTENT

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	200meq/100ml (2meq/ml) Solution; Intravenous					
	PREMIUM CONTENT					
10.	Cardizem 30mg, 60mg, 90mg, 120mg Tablet	Diltiazem Hydrochloride	PREMIUM CONTENT	Zydus Lifesciences	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
11.	Kengreal 50mg/Vial Powder; Intravenous	Cangrelor	PREMIUM CONTENT	Gland Pharma	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
12.	Emflaza 22.75mg/ml Suspension; Oral	Deflazacort	PREMIUM CONTENT	Upsher Smith Labs	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
13.	Norepinephrine Bitartrate In 5% Dextrose Eq 4mg Base/250ml (Eq 16mcg Base/ml) Eq 8mg Base/250ml (Eq 32mcg Base/ml) Solution; Intravenous	Norepinephrine Bitartrate	PREMIUM CONTENT	Sagent	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

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Tentative Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developer ²
1.	Promacta Eq 25mg Acid, Eq 12.5mg 50 mg and 75 mg Tablets Eq 100mg Acid Tablet	Eltrombopag Olamine	PREMIUM CONTENT	Somerset Therapeutics	-	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Caplyta 10.5, 21 mg Capsule Suitability Petition 14, 28 mg Capsule	Lumateperone Tosylate	PREMIUM CONTENT	Dr Reddy's	-	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Caplyta 42 mg Capsule	Lumateperone Tosylate	PREMIUM CONTENT	Dr Reddy's	-	PREMIUM CONTENT
	PREMIUM CONTENT					

² Other ANDA Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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LOW COMPETITION APPROVALS



14TH AUG – 20TH AUG, 2025

Final Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers Yet To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developers ³
1.	Retin-A 0.025% Cream; Topical	Tretinoin	PREMIUM CONTENT	Alembic	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Flonase Allergy Relief 0.05mg/Spray Spray, Metered; Nasal	Fluticasone Propionate	PREMIUM CONTENT	Rubicon	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					

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Tentative Approvals

<i>Sr. No</i>	<i>Brand Name</i>	<i>Generic Name</i>	<i>Para IV Filers To Be Approved</i>	<i>Approved Company Name</i>	<i>No. Of Final Approvals</i>	<i>Other ANDA Developer³</i>
1.	Janumet XR 500mg/50mg, 1gm/50mg, 100mg/1gm; Tablet ER	Sitagliptin Phosphate and Metformin Hydrochloride	PREMIUM CONTENT	Fosun Wanbang (Jiangsu) Pharmaceutical	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



21ST AUG – 27TH AUG, 2025

Final Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers Yet To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developers ⁴
1.	Opsumit 10mg Tablet	Macitentan	PREMIUM CONTENT	Alembic, MSN	2 nd , 3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Xeljanz Xr Eq 11mg Base Tablet, Extended Release	Tofacitinib Citrate	PREMIUM CONTENT	Ajanta Pharma	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Abraxane 100mg/Vial Powder; Intravenous	Paclitaxel	PREMIUM CONTENT	Mylan	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Protamine Sulfate 250mg/25ml (10mg/ml) Solution; Intravenous	Protamine Sulfate	PREMIUM CONTENT	Fresenius Kabi	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

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Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developer ⁴
1.	Xigduo Xr 2.5mg;1gm Tablet, Extended Release	Dapagliflozin; Metformin Hydrochloride	PREMIUM CONTENT	Macleods	None	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Xigduo Xr 5mg;500mg, 5mg;1gm 10mg;500mg, 10mg;1gm Tablet, Extended Release	Dapagliflozin; Metformin Hydrochloride	PREMIUM CONTENT	Macleods	None	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Firmagon 80 Mg/Vial And 120 Mg/Vial; Powder, Subcutaneous	Degarelix Acetate	PREMIUM CONTENT	Chia Tai Tianqing Pharmaceutical	None	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Edurant 2.5mg and 25mg Tablet	Rilpivirine	PREMIUM CONTENT	Somerset Therapeutics	None	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Ofev 100 mg and 150 mg Capsule	Nintedanib	PREMIUM CONTENT	Teva	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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