

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR JULY 2025



LOW COMPETITION APPROVALS



25TH JUN-02ND JULY, 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 ¹
1.	Meropenem 2gm/vial Powder; Intravenous	Meropenem	PREMIUM CONTENT	Brooks Steriscience	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Flo-Pred Eq 15mg Base/5ml	Prednisolone Acetate	PREMIUM CONTENT	Tulex Pharms	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Xarelto 1mg/ml For Suspension; Oral	Rivaroxaban	PREMIUM CONTENT	Alkem	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Ambisome 50mg/Vial Injectable, Liposomal	Amphotericin B	PREMIUM CONTENT	Mylan	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Carnitor 200mg/ML Injectable	Levocarnitine	PREMIUM CONTENT	Deva Holding	3 rd	PREMIUM CONTENT

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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Sr. No	Brand Name	Generic Name	Para IV Filers Yet To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developers ¹
	PREMIUM CONTENT					
6.	Myrbetriq 50mg Tablet, Extended Release	Mirabegron	PREMIUM CONTENT	Qilu pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Lotemax Sm 0.38% Gel; Ophthalmic	Loteprednol Etabonate	PREMIUM CONTENT	Lupin	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
8.	Emflaza 22.75mg/ML Suspension; Oral	Deflazacort	PREMIUM CONTENT	Aucta	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
9.	Cataflam 25 Mg Tablet; Oral	Diclofenac Potassium	PREMIUM CONTENT	Umedica	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					

Tentative Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developer ¹
1.	Biktarvy 50mg;200mg; 25mg	Bictegravir Sodium; Emtricitabine; Tenofovir	PREMIUM CONTENT	Cipla	-	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 ¹
	Tablet	Alafenamide Fumarate				
	PREMIUM CONTENT					
2.	Biktarvy 30mg;120mg; 15mg Tablet	Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate	PREMIUM CONTENT	Cipla	-	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Mycapssa 20mg Capsule, Delayed Release	Octreotide	PREMIUM CONTENT	Teva	-	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Xtandi 40 mg, 80 mg Tablet	Enzalutamide	PREMIUM CONTENT	Haimen Pharma (Sinotherapeutics)	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



03RD JULY – 09TH JULY, 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.	Nizoral 200 mg Tablet	Ketoconazole	PREMIUM CONTENT	Esjay Pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Manganese Chloride in Plastic Container Eq 0.1mg Manganese/ml Injectable; Injection	Manganese Chloride	PREMIUM CONTENT	Fresenius Kabi USA	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

Tentative Approvals

There are no Low Competition Tentative Approvals this week.

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



10TH JULY – 16TH JULY, 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.	Selenious Acid Eq 600mcg Selenium/10ml (Eq 60mcg Selenium/ml) Solution; Intravenous	Selenious Acid	PREMIUM CONTENT	Gland pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Metrocream 0.75% Cream; Topical	Metronidazole	PREMIUM CONTENT	Aurobindo Pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Retin-A 0.025% Cream; Topical	Tretinoin	PREMIUM CONTENT	Encube	3 rd	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 ³
1.	Orilissa 150 Mg,200mg Tablet	Elagolix Sodium	PREMIUM CONTENT	Hetero Labs	-	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Ofev 100 Mg,150 Mg Suitability Petition 25 mg	Nintedanib Esylate	PREMIUM CONTENT	Cipla	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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17TH JULY – 23RD JULY, 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.	Fycompa 0.5 mg/ml Suspension; Oral	Perampanel	PREMIUM CONTENT	MSN	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Namzaric 10mg;14mg 10mg;28mg	Donepezil Hydrochloride; Memantine Hydrochloride	PREMIUM CONTENT	Macleods, Xiamen	2 nd , 3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Sertraline Hydrochloride Eq 150mg Base, Eq 200mg Base	Sertraline Hydrochloride	PREMIUM CONTENT	Zenara	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Tribenzor Eq 5mg Base; 12.5mg;20mg, Eq 10mg Base; 12.5mg;40mg,	Amlodipine Besylate; Hydrochlorothiazide; Olmesartan Medoxomil	PREMIUM CONTENT	Macleods Pharms	4 th	PREMIUM CONTENT

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Sr. No	Brand Name	Generic Name	Para IV Filers Yet To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developers ⁴
	Eq 10mg Base; 25mg;40mg Tablet					
	PREMIUM CONTENT					
5.	Cancidas 50 mg/vial,70 mg/vial Powder, Intravenous	Caspofungin Acetate	PREMIUM CONTENT	Hangzhou Zhongmei	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Arranon (Injectable; Intravenous) Suitability Petition 375mg/75ml (5mg/ml)	Nelarabine	PREMIUM CONTENT	Shorla	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Lariam 250mg Tablet	Mefloquine Hydrochloride	PREMIUM CONTENT	Chartwell Rx	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					

Tentative Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developer ⁴
1.	Janumet 500mg;50mg, 1gm;50mg Tablet	Metformin Hydrochloride; Sitagliptin Phosphate	PREMIUM CONTENT	MSN	-	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
	PREMIUM CONTENT					
2.	Synjardy 5mg;500mg, 5mg;1gm, 12.5mg;500mg, 12.5mg;1gm Tablet	Empagliflozin; Metformin Hydrochloride	PREMIUM CONTENT	Macleods Pharms	-	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Bridion Eq 500mg Base/5ml (Eq 100mg Base/ml), Eq 200mg Base/2ml (Eq 100mg Base/ml) Injection	Sugammadex	PREMIUM CONTENT	Tamarang	-	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Inlyta 1 mg,5mg Tablet	Axitinib	PREMIUM CONTENT	Glenmark	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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24TH JULY – 30TH JULY, 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 ⁵
1.	Selenious Acid Eq 12mcg Selenium/2ml (Eq 6mcg Selenium/ml) Solution; Intravenous	Selenious Acid	PREMIUM CONTENT	Cipla	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Prezista 75 mg,150mg and 300 mg Tablet	Darunavir	PREMIUM CONTENT	Mylan	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Prezista 400mg and 600mg Tablet	Darunavir	PREMIUM CONTENT	Mylan	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Glucagon 1mg/Vial Injectable; Injection	Glucagon	PREMIUM CONTENT	Lupin	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					

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Sr. No	Brand Name	Generic Name	Para IV Filers Yet To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developers ⁵
5.	Victoza 18mg/3ml (6mg/ml) Solution; Subcutaneous	Liraglutide	PREMIUM CONTENT	Lupin	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Brilinta 60 mg Tablet	Ticagrelor	PREMIUM CONTENT	Sunshine	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					

Tentative Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developer ⁵
1.	Cabometyx 20mg, 40mg and 60mg Tablet	Cabozantinib	PREMIUM CONTENT	MSN Labs	1	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Zeposia 0.23mg, 0.46mg, and 0.92 mg Capsule	Ozanimod Hydrochloride	PREMIUM CONTENT	Synthon Pharma	-	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 ⁵
3.	Januvia 25mg, 50mg and 100mg Tablet	Sitagliptin Phosphate	PREMIUM CONTENT	MSN Labs	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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