

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR JUNE 2025



LOW COMPETITION APPROVALS



28TH MAY – 03RD JUN, 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.	Bosulif Eq 100mg, Eq 500mg Base Tablet	Bosutinib Monohydrate	PREMIUM CONTENT	Alembic	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Topamax Sprinkle 50mg Capsule	Topiramate	PREMIUM CONTENT	Rubicon	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Relistor 12mg/0.6ml (12mg/0.6ml) Solution	Methylnaltrexone Bromide	PREMIUM CONTENT	Mylan	1 st	PREMIUM CONTENT
	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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LOW COMPETITION APPROVALS



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.	Lynparza 100mg, 150mg Tablet	Olaparib	PREMIUM CONTENT	Sandoz	-	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Caplyta 10.5, 21 mg Capsule & Suitability Petition 14, 28 mg Capsule	Lumateperone	PREMIUM CONTENT	Alkem	-	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Caplyta 42 mg Capsule	Lumateperone	PREMIUM CONTENT	Alkem	-	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Ubrelevy 50mg, 100mg Tablet	Ubrogepant	PREMIUM CONTENT	Aurobindo	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



04TH JUN – 10TH JUN, 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.	Giapreza Eq 2.5mg Base/ml (Eq 2.5mg Base/ml) Injection	Angiotensin II Acetate	PREMIUM CONTENT	Gland Pharma	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Epinephrine 1mg/ml (1mg/ml) Solution; Intravenous, Intraocular, Intramuscular, Subcutaneous	Epinephrine	PREMIUM CONTENT	Gland Pharma	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Janumet XR 500mg; Eq 50mg Base, 1gm; Eq 50mg Base, 1gm; Eq 100mg Base Tablet, Extended Release	Metformin Hydrochloride; Sitagliptin Phosphate	PREMIUM CONTENT	Anchen	1 st	PREMIUM CONTENT

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	PREMIUM CONTENT					
4.	Kuvan 100 Mg Tablet	Sapropterin Dihydrochloride	PREMIUM CONTENT	Aurobindo	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Flonase 0.05 Mg/Spray Metered Nasal	Fluticasone Propionate	PREMIUM CONTENT	Rubicon	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.	Xifaxan 550 mg Tablet	Rifaximin	PREMIUM CONTENT	Zydus	-	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
	PREMIUM CONTENT					
2.	Xifaxan 200 mg Tablet	Rifaximin	PREMIUM CONTENT	Zydus	-	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Mavenclad 10 mg Tablet	Cladribine	PREMIUM CONTENT	Apotex	-	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Xcopri 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg ; Tablet	Cenobamate	PREMIUM CONTENT	Zenara Pharma	-	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Lynparza 100mg, 150mg Tablet	Olaparib	PREMIUM CONTENT	Cipla	-	PREMIUM CONTENT

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	PREMIUM CONTENT					
6.	Fycompa 2mg, 4mg, 6mg, 8mg, 10mg, 12mg Tablet	Perampanel	PREMIUM CONTENT	Sun (Taro)	1	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Eucrisa 2% Ointment	Crisaborole	PREMIUM CONTENT	Macleods	-	PREMIUM CONTENT
	PREMIUM CONTENT					
8.	Oxtellar XR 150mg, 300mg, 600mg Tablet, Extended Release	Oxcarbazepine	PREMIUM CONTENT	Novast	3	PREMIUM CONTENT
	PREMIUM CONTENT					
9.	Mayzent 0.25mg, 1mg, 2 mg Tablet	Siponimod	PREMIUM CONTENT	Dr Reddy's	-	PREMIUM CONTENT

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	PREMIUM CONTENT					
10.	Jardiance 10mg, 25mg Tablet <u>Suitability Petition</u> 2.5 mg Tablet	Empagliflozin	PREMIUM CONTENT	Ajanta	-	PREMIUM CONTENT
	PREMIUM CONTENT					
11.	Myrbetriq 25 Mg Tablet, Extended Release	Mirabegron	PREMIUM CONTENT	Ascent Pharms	4	PREMIUM CONTENT
	PREMIUM CONTENT					
12.	Myrbetriq 50 Mg Tablet, Extended Release	Mirabegron	PREMIUM CONTENT	Ascent Pharms	4	PREMIUM CONTENT
	PREMIUM CONTENT					
13.	Onureg 200 mg, 300 mg Tablet	Azacitidine	PREMIUM CONTENT	Teva	-	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
	PREMIUM CONTENT					
14.	Vyndamax 61 mg Capsule	Tafamidis	PREMIUM CONTENT	Apotex	-	PREMIUM CONTENT
	PREMIUM CONTENT					
15.	Nucynta 20mg/ml Oral Solution	Tapentadol Hydrochloride	PREMIUM CONTENT	Novitium Pharma	-	PREMIUM CONTENT
	PREMIUM CONTENT					
16.	Caplyta 10.5,21 mg Capsule	Lumateperone Tosylate	PREMIUM CONTENT	Hetero	-	PREMIUM CONTENT
	PREMIUM CONTENT					
17.	Caplyta 42mg Capsule Suitability Petition	Lumateperone Tosylate	PREMIUM CONTENT	Hetero	-	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
	14, 28 mg Capsule					
	PREMIUM CONTENT					
18.	Selenious Acid Eq 12mcg Selenium/2ml Solution ; Intravenous	Selenious Acid	PREMIUM CONTENT	Steriscience	-	PREMIUM CONTENT
	PREMIUM CONTENT					
19.	Selenious Acid Eq 60mcg Selenium/ml Solution ; Intravenous	Selenious Acid	PREMIUM CONTENT	Steriscience	1	PREMIUM CONTENT
	PREMIUM CONTENT					
20.	Selenious Acid Eq 600mcg Selenium/10ml Solution	Selenious Acid	PREMIUM CONTENT	Steriscience	2	PREMIUM CONTENT
	PREMIUM CONTENT					

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



11TH JUN – 17TH JUN, 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.	Magnesium Sulfate 1gm/2ml (500mg/ml) 5gm/10ml (500mg/ml) 10gm/20ml (500mg/ml) 25gm/50ml (500mg/ml) Solution; Intramuscular, Intravenous	Magnesium Sulfate	PREMIUM CONTENT	Aspiro	1 st 2 nd 2 nd 1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Precedex Eq 1mg Base/250ml	Dexmedetomidine Hydrochloride	PREMIUM CONTENT	Hikma	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Zyloprim 200 mg Tablet	Allopurinol	PREMIUM CONTENT	Indoco	2 nd	PREMIUM CONTENT

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	PREMIUM CONTENT					
4.	Kayexalate 15gm/60ml Suspension; Oral Suitability Petition	Sodium Polystyrene Sulfonate	PREMIUM CONTENT	Lyne	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Pred Forte 1% Suspension/Drops; Ophthalmic	Prednisolone Acetate	PREMIUM CONTENT	Amneal	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Selenious Acid Eq 12mcg Selenium/2ml Solution; Intravenous	Selenious Acid	PREMIUM CONTENT	Aspiro	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Selenious Acid Eq 600mcg Selenium/10ml Solution; Intravenous	Selenious Acid	PREMIUM CONTENT	Aspiro	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
8.	Qsymia Eq 3.75mg Base;23mg, Eq 7.5mg Base;46mg,	Phentermine Hydrochloride; Topiramate	PREMIUM CONTENT	Dr Reddys	2 nd	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 ³
	Eq 11.25mg Base;69mg, Eq 15mg Base;92mg, Capsule, Extended Release					
	PREMIUM CONTENT					
9.	Xadago Eq 50mg Base Eq 100mg Base Tablet	Safinamide Mesylate	PREMIUM CONTENT	Zenara	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 ¹
1.	Oxtellar XR 150mg,300mg Tablet, Extended Release	Oxcarbazepine	PREMIUM CONTENT	Lupin	3	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Oxtellar XR 600mg Tablet, Extended Release	Oxcarbazepine	PREMIUM CONTENT	Lupin	3	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
	PREMIUM CONTENT					
3.	Tracleer 32 mg Tablet for suspension, Oral	Bosentan	PREMIUM CONTENT	Zydus	1	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Triumeq Eq 600mg Base; Eq 50mg Base;300mg Tablet	Abacavir Sulfate; Dolutegravir Sodium; Lamivudine	PREMIUM CONTENT	Cipla, Hetero	-	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Selenious Acid Eq 600mcg Selenium/10ml Solution, Intravenous	Selenious Acid	PREMIUM CONTENT	Xiromed	2	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Dovato 50mg, 300mg	Dolutegravir Sodium; Lamivudine	PREMIUM CONTENT	Emcure	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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18TH JUN – 24TH JUN, 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.	Ambisome 50mg/Vial Injectable, Liposomal	Amphotericin B	PREMIUM CONTENT	Avet Lifesciences	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Zyloprim 200 mg Tablet	Allopurinol	PREMIUM CONTENT	Zydus	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Ozobax Ds 10mg/5ml Solution; Oral	Baclofen	PREMIUM CONTENT	Rubicon	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 ¹
1.	Rytary 23.75mg;95mg, 36.25mg;145mg, 48.75mg;195mg Capsule, Extended Release	Carbidopa, Levodopa	PREMIUM CONTENT	Dr Reddy	-	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Rytary 61.25mg/ 245mg Capsule, extended release	Carbidopa, Levodopa	PREMIUM CONTENT	Dr Reddy	-	PREMIUM CONTENT
	PREMIUM CONTENT					

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