

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR SEPTEMBER 2025



LOW COMPETITION APPROVALS



28TH AUG – 03RD SEPT, 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.	Sodium Bicarbonate in Plastic Container Suitability Petition 0.5meq/ml Injectable	Sodium Bicarbonate	PREMIUM CONTENT	Fresenius Kabi	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Amicar 250mg/ml Injectable	Aminocaproic Acid	PREMIUM CONTENT	Gen Ilac	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Saxenda 18mg/3ml (6mg/ml) Solution; Subcutaneous	Liraglutide	PREMIUM CONTENT	Teva	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 Approval

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Other ANDA Developer ¹
1.	Bridion 100mg/1ml Solution; Intravenous	Sugammadex Sodium	PREMIUM CONTENT	USV	3	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Januvia 25, 50 And 100 Mg Tablet	Sitagliptin Phosphate	PREMIUM CONTENT	Biocon	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



04TH SEPT–10TH SEPT, 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.	Zanaflex Suitability Petition Eq 8mg Base Capsule	Tizanidine Hydrochloride	PREMIUM CONTENT	Rubicon Research	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Risperdal Consta 12.5, 25, 37.5, 50 mg/vial Injectable	Risperidone	PREMIUM CONTENT	Nanomi, Amneal	2 nd , 3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Votrient Eq 400mg base Tablet	Pazopanib Hydrochloride	PREMIUM CONTENT	Torrent	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Thiola EC 100mg	Tiopronin	PREMIUM CONTENT	Amneal	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 ²
	Tablet, Delayed Release					
	PREMIUM CONTENT					
5.	Bridion Eq 500mg Base/5ml (Eq 100mg Base/ml) Solution; Intravenous	Sugammadex Sodium	PREMIUM CONTENT	Aspiro Pharma	1 st	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 ²
1.	Wakix 4.45 and 17.8 mg Tablet	Pitolisant Hydrochloride	PREMIUM CONTENT	Annora Pharma	None	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Hetlioz LQ 4 mg/ml Suspension	Tasimelteon	PREMIUM CONTENT	MSN Labs	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



11TH SEPT–17TH SEPT, 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.	Stromectol 3mg Tablet	Ivermectin	PREMIUM CONTENT	Epic Pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Benadryl 50mg/ml Injectable	Diphenhydramine Hydrochloride	PREMIUM CONTENT	Micro Labs	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

There are no Low Competition Tentative Approvals this week.

³ 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



18TH SEPT–24TH SEPT, 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.	Sodium Acetate 100meq/50ml (2meq/ml) 200meq/100ml (2meq/ml) Solution; Intravenous	Sodium Acetate	PREMIUM CONTENT	Somerset Theraps	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Imodium A-D 1mg/7.5ml Solution; Oral	Loperamide Hydrochloride	PREMIUM CONTENT	Bionpharma	2 th	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Campral 333mg Tablet, Delayed Release	Acamprosate Calcium	PREMIUM CONTENT	Bionpharma	4 th	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 ⁴
4.	Endometrin 100mg Insert; Vaginal	Progesterone	PREMIUM CONTENT	Xiromed	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Oriahnn (copackaged) 300 mg, 1mg, and 0.5mg; 300 mg Capsule	Elagolix sodium, estradiol and norethindrone acetate; Elagolix sodium	PREMIUM CONTENT	Teva	1 st	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.	Farxiga 5,10 mg Tablet	Dapagliflozin	PREMIUM CONTENT	Aurobindo	None	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Xeljanz 5 mg Tablet	Tofacitinib	PREMIUM CONTENT	Aurobindo	None	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
3.	Saxenda 18mg/3ml (6mg/ml) Prefilled Syringe Injection	Liraglutide	PREMIUM CONTENT	Orbicular	1	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Triumeq PD 60mg/5mg/30mg Tablet for Suspension	Abacavir Sulfate, Dolutegravir and Lamivudine	PREMIUM CONTENT	Macleods	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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