

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR OCTOBER 2025



LOW COMPETITION APPROVALS



25TH SEPT – 02ND OCT, 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.	Lumigan 0.01% Solution/Drops, Ophthalmic	Bimatoprost	PREMIUM CONTENT	Amneal	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Xarelto 1mg/ml Suspension; Oral	Rivaroxaban	PREMIUM CONTENT	Lupin	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Foscavir 12gm/500ml Solution; Intravenous	Foscarnet Sodium	PREMIUM CONTENT	Hospira	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

There are no Low Competition Tentative Approvals this week

¹Other 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



03RD OCT–08TH OCT, 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.	Mifeprex 200mg Tablet	Mifepristone	PREMIUM CONTENT	Evita Solutions	2 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Remeron Suitability Petition 7.5mg Tablet	Mirtazapine	PREMIUM CONTENT	Annora Pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Isopto Carpine 1%, 2% and 3% Solution; Ophthalmic	Pilocarpine Hydrochloride	PREMIUM CONTENT	FDC	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Rayos 1 mg and 2 mg Tablet, Delayed Release	Prednisone	PREMIUM CONTENT	Dr Reddy's	2 nd	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 ²
5.	Vancomycin Hydrochloride Eq 750mg Base/Vial, Eq 1.25gm Base/Vial, Eq 1.5gm Base/Vial Powder; Intravenous	Vancomycin Hydrochloride	PREMIUM CONTENT	Steriscience	2 nd , 4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Intelence 100mg, 200mg Tablet	Etravirine	PREMIUM CONTENT	Bionpharma	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Emflaza 22.75mg/ml Suspension; Oral	Deflazacort	PREMIUM CONTENT	Zydus Lifesciences	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
8.	Epinephrine 30mg/30ml (1mg/ml) Solution; Intramuscular, Intravenous, Subcutaneous	Epinephrine	PREMIUM CONTENT	Gland pharma	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					

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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 ²
1.	Invokamet Xr 50mg;500mg, 50mg;1gm, 150mg;500mg, 150mg;1gm	Canagliflozin; Metformin Hydrochloride	PREMIUM CONTENT	Macleods	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



09TH OCT–15TH OCT, 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.	Absorica 25 mg and 35 mg Capsule	Isotretinoin	PREMIUM CONTENT	Amneal	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Naropin 20mg/10ml (2mg/ml) Solution; Injection	Ropivacaine Hydrochloride	PREMIUM CONTENT	Neocubes Pharma	4 th	PREMIUM CONTENT
	PREMIUM CONTENT					

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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 ³
1.	Lokelma 5g, 10g/ packet Oral suspension	Sodium Zirconium Cyclosilicate	PREMIUM CONTENT	Alkem Labs	None	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Xeljanz 1 mg/ml Oral Solution	Tofacitinib	PREMIUM CONTENT	Sun Pharm	None	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Inlyta 1mg and 5mg Tablet	Axitinib	PREMIUM CONTENT	Sandoz	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



16TH OCT–29TH OCT, 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.	Thorazine 30mg/ml 100mg/ml Concentrate Oral	Chlorpromazine Hydrochloride	PREMIUM CONTENT	Rubicon	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Adrenalin Eq 30mg Base/30ml (Eq 1mg Base/ml) Solution; Intramuscular, Intravenous, Subcutaneous	Epinephrine	PREMIUM CONTENT	Amneal	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Premarin 0.3mg, 0.45mg, 0.625mg, 0.9mg, 1.25mg Tablet; Oral	Estrogens, Conjugated	PREMIUM CONTENT	Novast Labs	1 st	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
	PREMIUM CONTENT					
4.	Tigan 100mg/ml Injectable; Injection	Trimethobenzamide Hydrochloride	PREMIUM CONTENT	BPI Labs	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Cardene In 0.86% Sodium Chloride In Plastic Container And Cardene 0.83% Sodium Chloride In Plastic Container 40mg/200ml (0.2mg/ml), 20mg/200ml (0.1mg/ml) Injectable Intravenous	Nicardipine Hydrochloride	PREMIUM CONTENT	Caplin	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Lucemyra Eq 0.18mg Base Tablet	Lofexidine Hydrochloride	PREMIUM CONTENT	Novitium Pharma	3 rd	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Dalvance Eq 500mg Base/Vial Powder; Intravenous	Dalbavancin Hydrochloride	PREMIUM CONTENT	Teva	1 st	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
	PREMIUM CONTENT					
8.	Atropine Sulfate 0.4mg/ml (0.4mg/ml), 1mg/ml (1mg/ml) Solution; Intravenous	Atropine Sulfate	PREMIUM CONTENT	Hikma	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.	Xeljanz 10mg Tablet	Tofacitinib	PREMIUM CONTENT	Aurobindo	None	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Farxiga 5mg,10mg Tablet	Dapagliflozin	PREMIUM CONTENT	Macleods	None	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Descovy 200mg; Eq 25mg Base, Tablet	Emtricitabine; Tenofovir Alafenamide Fumarate	PREMIUM CONTENT	Cipla	1	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					
4.	Descovy 120mg; Eq 15mg Base Tablet	Emtricitabine; Tenofovir Alafenamide Fumarate	PREMIUM CONTENT	Cipla	None	PREMIUM CONTENT
	PREMIUM CONTENT					
5.	Janumet Xr 500mg/50mg, 1gm/50mg, 100mg/1gm Tablet ER	Sitagliptin Phosphate and Metformin Hydrochloride	PREMIUM CONTENT	Sinotherapeutics	None	PREMIUM CONTENT
	PREMIUM CONTENT					
6.	Biktarvy 50mg;200mg; 25mg Tablet	Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate	PREMIUM CONTENT	Cipla	None	PREMIUM CONTENT
	PREMIUM CONTENT					
7.	Biktarvy 30 mg;120 mg; 15 mg Tablet	Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate	PREMIUM CONTENT	Cipla	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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8.	Aklief 0.005% Cream	Trifarotene	PREMIUM CONTENT	Taro pharma	None	PREMIUM CONTENT
	PREMIUM CONTENT					
9.	Nexlizet 10mg, 180mg Tablet	Bempedoic Acid, Ezetimibe	PREMIUM CONTENT	Alkem	None	PREMIUM CONTENT
	PREMIUM CONTENT					
10.	Jynarque 90 mg Tablet	Tolvaptan	PREMIUM CONTENT	Alkem	1	PREMIUM CONTENT
	PREMIUM CONTENT					

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LOW COMPETITION APPROVALS



30TH OCT–05TH NOV, 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.	Gleostine 10 mg, 40 mg and 100 mg Capsule	Lomustine	PREMIUM CONTENT	Carnegie	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Angeliq 0.5mg;1mg Tablet	Drospirenone; Estradiol	PREMIUM CONTENT	Novast Labs	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Cortisporin 1%; Eq 3.5mg Base/ml;10,000 Units/ml Solution/Drops;Otic	Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate	PREMIUM CONTENT	Amneal	3 rd	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
1.	Qvar 0.08 mg/INH Aerosol, metered, Inhalation	Beclomethasone Dipropionate	PREMIUM CONTENT	Amneal	None	PREMIUM CONTENT
	PREMIUM CONTENT					

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