

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR FEBRUARY 2025



LOW COMPETITION APPROVAL



5TH FEB -18TH FEB 2025

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Stromectol 6, 3 mg ; Tablet	Ivermectin	Naturally sourced ingredients	Rubicon	3 rd for 3 mg 1 st for 6 mg	All patents have expired. All three companies have already launched their generics.
2.	Potassium Phosphates 1.18gm/5ml;1.12gm/5ml, 3.54gm/15ml;3.36gm/15ml, 11.8gm/50ml ;11.2gm/50ml	Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic	None	Cipla	4 th	<div style="background-color: #cccccc; padding: 20px; text-align: center;"> <p>Premium Report</p> </div>
3.	Dyazide 25 ; 37.5 mg ; Capsule	Hydrochlorothiazide; Triamterene	None	Macleods	4 th	
4.	Afinitor Disperz 2,3,5 mg; Tablet For Suspension	Everolimus	None	Natco	3 rd	
5.	Lotemax 0.5% Suspension/Drops ; Ophthalmic	Loteprednol Etabonate	None	Padagis	4 th	

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LOW COMPETITION APPROVAL



Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
6.	Buprenex Eq 0.3mg Base/ml	Buprenorphine Hydrochloride	Controlled Substances	Somerset	4 th	Premium Report
7.	Ultram ER 100, 200, 300 mg Tablet, Extended Release	Tramadol Hydrochloride	Controlled Substances	Macleods	2 nd	
8.	Alinia 500 mg ; Tablet	Nitazoxanide	None	Zenara	2 nd	
9.	PRONESTYL 500 mg/ml	PROCAINAMIDE HYDROCHLORIDE	None	Caplin	4 th	
10.	Tracleer 32 mg; Tablet for suspension, Oral	Bosentan	None	Natco	1 st	

Tentative Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Hemangeol 4.28 mg/mL; Oral Solution	Propranolol Hydrochloride	None	Rubicon	-	Premium Report

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2.	Lynparza 100 and 150mg; Tablet	Olaparib	None	Qilu	-	Premium Report
3.	Edarbi 40, 80 mg; Tablet	Azilsartan Kamedoxomil	None	Saba Ilac Sanayive	-	
4.	Symtuza 800 mg/150 mg/ 200 mg/10 mg ; Tablets	Darunavir, Cobicistat, Emtricitabine, Tenofovir Alafenamide	Polymeric Compounds	Lupin	-	
5.	Motegrity EQ 1, 2 mg Base	Prucalopride Succinate	None	SKG Pharma	1	

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6.	Synjardy 5mg;500mg/1gm, 12.5mg;500mg/1gm, Tablet, Oral	Empagliflozin and Metformin HCL	None	Ajanta Pharma	-	Premium Report
7.	ZITUVIMET 500MG;50MG, 1GM;50MG Tablet	METFORMIN HYDROCHLORIDE; SITAGLIPTIN	None	Dr Reddy's	-	
8.	Mayzent 0.25mg, 1mg, 2 mg Tablet	Siponimod Fumaric Acid	Molecular weight greater than 1000 Daltons	Cipla	-	
9.	Xeljanz 1 mg/mL ; Oral Solution	Tofacitinib	None	Annora Pharma	-	
10.	Descovy 200mg/ 25mg; Tablet	Emtricitabine and Tenofovir Alafenamide Fumarate	Polymeric Compounds	Macleods	1	

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LOW COMPETITION APPROVAL



12TH FEB – 18TH FEB 2025

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Mucomyst 20, 10% Solution ; Inhalation	Acetylcysteine	None	Somerset	4 th	Premium Report
2.	Efudec 5% Cream ; Topical	Fluorouracil	None	Encube	4 th	
3.	Prohance 279.3 mg/ml Injectable ; Injection	Gadoteridol	None	Hainan Poly	1 st	
4.	Prograf Eq 5mg Base/mL Injectable ; Injection	Tacrolimus	Naturally sourced ingredients	Nexus	1 st	
5.	Succinylcholine Chloride 100 mg / 5 mL Solution ; Intramuscular, Intravenous	Succinylcholine Chloride	None	Fresenius Kabi	3 rd	

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LOW COMPETITION APPROVAL



<i>Sr. No</i>	<i>Brand Name</i>	<i>Generic Name</i>	<i>Drug Complexity</i>	<i>Company Name</i>	<i>No. of final approvals</i>	<i>Opportunity</i>
6.	Selenious Acid Eq 600mcg Selenium/10ml ; Solution, Intravenous	Selenious Acid	None	Fresenius Kabi	1 st	Premium Report

There are no Low Competition Tentative Approvals this week.

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LOW COMPETITION APPROVAL



19TH FEB – 25TH FEB 2025

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Asacol HD 800 mg ; Tablet, Delayed Release	Mesalamine	Targeted Orals , Controlled Substances	Amneal	3 rd	Premium Report
2.	Suboxone 2;0.5 mg, 4;1 mg Film, Buccal, Sublingual	Buprenorphine Hydrochloride and Naloxone Hydrochloride	Controlled Substances	Aveva (Difgen Pharma)	4 th	
3.	Lucemyra Eq 0.18 mg Base Tablet	Lofexidine Hydrochloride	None	MSN	2 nd	
4.	CaroSpir 25 mg/ 5mL Oral Suspension	Spirolactone	None	Hetero	2 nd	

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Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
5.	Biorphen 0.5mg/5ml (0.1mg/ml) Solution ; Intravenous	Phenylephrine Hydrochloride	None	Somerset	1 st	Premium Report
6.	Selenious Acid Eq 600mcg Selenium/10ml ; Solution, Intravenous	Selenious Acid	None	Sun Pharma	2 nd	
7.	Cosopt Pf Eq 2% Base; Eq 0.5% Base Solution/Drops; Ophthalmic	Dorzolamide Hydrochloride; Timolol Maleate	None	Identirx	4 th	

Tentative Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Brilinta 90 mg ; Tablet	Ticagrelor	None	Apotex	3	Premium Report

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Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
2.	Brilinta 60 mg ; Tablet	Ticagrelor	None	Apotex	3	Premium Report
3.	Rytary 23.75/95mg, 36.25/145mg, 48.75/195mg, 61.25mg/ 245mg Capsule, Extended Release	Carbidopa and Levodopa	None	Ascent Pharms	-	
4.	Rexulti 0.25, 0.5, 1, 2, 3, 4 mg; Tablet	Brexipiprazole	None	Macleods	1	
5.	Imbruvica 140 mg; Capsule	Ibrutinib	None	Hetero	1	
6.	Jevtana Kit 60MG/1.5ML; Solution, Intravenous	Cabazitaxel	Naturally sourced ingredients	Eugia	2	

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Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
7.	Wakix 4.45 And 17.8 Mg; Tablet	Pitolisant Hydrochloride	None	Zenara Pharma	-	Premium Report
8.	Motegrity Eq 1mg Base, Eq 2mg Base ; Tablet	Prucalopride Succinate	None	Annora	1	

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