

LOW COMPETITION APPROVALS THIS WEEK

COMBINED REPORT FOR AUGUST 2024



LOW COMPETITION APPROVAL



31ST JUN - 6TH AUG 2024

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Pred Forte 1%, Suspension/Drops ; Ophthalmic	Prednisolone Acetate	None	Lupin	1 st	All patents have expired. Lupin can launch anytime under CGT Exclusivity .
2.	Vagifem 10 mcg; Tablet,Vaginal	Estradiol	None	Aurobindo	4 th	Total US sales - \$316m. All patents have expired. Other three companies have already launched their generics. Aurobindo can launch anytime.
3.	Lodine 200, 300 mg Capsule	Etodolac	None	IPCA Labs	4 th	Premium Content
4.	Pantoprazole Sodium Eq 40mg Base/vial Powder ; Intravenous	Pantoprazole Sodium	None	Fresenius Kabi	1 st	
5.	Prolensa EQ 0.07% Acid; Solution/Drops, Ophthalmic	Bromfenac Sodium	None	Amneal	4 th	

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LOW COMPETITION APPROVAL



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6.	Ultram 100mg Tablet	Tramadol Hydrochloride	Controlled Substances	Graviti Pharms	2 nd	Premium Content
7.	Polytrim 10,000 units/ml; Eq 1mg base/ml Solution/Drops ; Ophthalmic	Polymyxin B Sulfate; Trimethoprim Sulfate	Polymeric Compounds	Somerset	4 th	

There are no Low Competition Tentative Approvals this week.

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LOW COMPETITION APPROVAL



07TH AUG -13TH AUG 2024

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Ophthaine 0.5% Solution / Drops ; Ophthalmic	Proparacaine Hydrochloride	None	Somerset	4 th	Premium Content
2.	Alphagan P 0.1% ; Ophthalmic Solution	Brimonidine Tartrate	None	Somerset	4 th	
3.	Ingrezza 40, 80 mg; Capsule, Oral	Valbenazine Tosylate	None	Zydus Cadila	2 nd	
4.	Ingrezza 60 mg; Capsules	Valbenazine Tosylate	None	Zydus Cadila	2 nd	
5.	Mekinist 0.5 mg and 2 mg ; Tablet	Trametinib	None	Novugen	1 st	

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6.	Soriatane 17.5mg Capsule	Acitretin	None	Alembic	4 th	Premium Content
7.	Opsumit 10 mg; Tablet, Oral	Macitentan	None	Torrent	1 st	
8.	Sprycel 20, 50, 70, 100 mg; Tablet	Dasatinib	None	Apotex	1 st	
9.	Fintepla 2.2 mg/mL ; Solution	Fenfluramine Hydrochloride	Controlled Substance	Apotex	1 st	

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Tentative Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Rayos 5 mg; Tablet, Delayed Release	Prednisone	None	Dr Reddy's	1	Premium Content
2.	Invokana 100,300 mg; Tablet, Oral	Canagliflozin	None	Macleods	-	
3.	Edarbyclor 40 mg/12.5 mg and 40 mg/25 mg ; Tablet	Azilsartan Medoxomil and Chlorthalidone	None	Teva	-	
4.	Briviact 10 mg/ml; Solution, Oral	Brivaracetam	Controlled Substance	Hainan Poly	-	

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LOW COMPETITION APPROVAL



14TH AUG -20TH AUG 2024

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Dolobid 250mg Tablet	Diflunisal	None	Heritage Pharma	1 st	Premium Content
2.	Dolobid 375mg Tablet SUITABILITY PETITION	Diflunisal	None	Heritage Pharma	1 st	
3.	Pradaxa 110mg Capsule	Dabigatran Etexilate Mesylate	None	Hetero	4 th	
4.	Brilinta 90mg Tablet	Ticagrelor	None	Prinston Pharma	3 rd	
5.	Midazolam in 0.9% Sodium Chloride 50 mg/50 mL and 100 mg/100 mL ; Intravenous	Midazolam	Controlled Substances	Gland Pharma	2 nd	

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6.	Bepreve 1.5% ; Solution/Drops, Ophthalmic	Bepotastine Besilate	None	Somerset	4 th	Premium Content
7.	Tranexamic Acid 1gm/100ml (10mg/ml) Intravenous Solution	Tranexamic Acid	None	Fresenius Kabi	4 th	
8.	Naropin 5mg/ml Solution, Injection	Ropivacaine Hydrochloride	None	Hikma	3 rd	
9.	Tykerb Eq 250mg Base Tablet	Lapatinib Ditosylate	None	Teva	2 nd	
10.	Colestid 1gm Tablet	Colestipol Hydrochloride	Polymeric Compounds	Edenbridge Pharms	4 th	

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1.	Briviact 25, 50, 75, 100 mg Tablet	Brivaracetam	Controlled Substances	Zhejiang	2	Premium Content
2.	SYNJARDY 5mg;500mg/1gm, 12.5mg;500mg/1gm, Tablet	Empagliflozin and Metformin HCL	None	Macleods	-	
3.	Lumify (OTC) 0.025% Ophthalmic Solution	Brimonidine Tartrate	None	Lupin	1	

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LOW COMPETITION APPROVAL



21ST AUG -27TH AUG 2024

Final Approvals

Sr. No	Brand Name	Generic Name	Drug Complexity	Company Name	No. of final approvals	Opportunity
1.	Onexton 3.75%; Eq 1.2% Base; Gel, Topical	Clindamycin Phosphate and Benzoyl Peroxide	Naturally sourced ingredients	Padagis (Perrigo)	2 nd	Premium Content
2.	Tepadina 15 mg/vial Powder; Intracavitary, Intravenous, Intravesical	Thiotepa	None	Beloteca	4 th	
3.	Lucemyra Eq 0.18 mg Base Tablet	Lofexidine Hydrochloride	None	Indoco	1 st	
4.	Asacol HD 800mg ; Tablet, Delayed Release;Oral	Mesalamine	Targeted Orals , Controlled Substances	Teva	2 nd	
5.	Luxiq 0.12% Aerosol, Foam; Topical	Betamethasone Valerate	None	Alembic	4 th	
6.	Tiglutik Kit 50 mg/10 mL; Oral Suspension	Riluzole	None	Alkem	1 st	

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1.	Vyndamax 61mg; Capsule	Tafamidis	None	Zenara Pharma	-	Premium Content

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