

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	All patents have expired. Other three companies have already launched their generics. IPCA can launch anytime.
4.	Pantoprazole Sodium Eq 40mg Base/vial Powder ; Intravenous	Pantoprazole Sodium	None	Fresenius Kabi	1 st	All patents have expired. Fresenius can launch anytime likely under CGT Exclusivity .
5.	Prolensa EQ 0.07% Acid; Solution/Drops, Ophthalmic	Bromfenac Sodium	None	Amneal	4 th	Total US sales - \$113m. There are total 10 Para IV filers. Litigation is settled with all. 4 generic companies including Amneal have already launched their generic product.

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6.	Ultram 100mg Tablet	Tramadol Hydrochloride	Controlled Substances	Graviti Pharms	2 nd	All patents have expired. Other strength of this drug is already genericized. Rubicon has already launched this strength. Graviti can launch anytime.
7.	Polytrim 10,000 units/ml; Eq 1mg base/ml Solution/Drops ; Ophthalmic	Polymyxin B Sulfate; Trimethoprim Sulfate	Polymeric Compounds	Somerset	4 th	All patents have expired. Other three companies have already launched their generics. Somerset can launch anytime.

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	All patents have expired. Other three companies have launched their generic. Somerset can launch anytime.
2.	Alphagan P 0.1% ; Ophthalmic Solution	Brimonidine Tartrate	None	Somerset	4 th	Total US sales - \$ 184m. All patents have expired. Three companies have already launched their generics. Somerset can launch anytime.
3.	Ingrezza 40, 80 mg; Capsule, Oral	Valbenazine Tosylate	None	Zydus Cadila	2 nd	Total US sales - \$ 1836m. There are 4 FTFs and litigation is settled with all including Zydus. Zydus and all other three companies can launch its generic under shared 180 days exclusivity on Mar 01, 2038.
4.	Ingrezza 60 mg; Capsules	Valbenazine Tosylate	None	Zydus Cadila	2 nd	Total US sales - \$ 1836m. There are two Para IV filers. Litigation is settled with both. Zydus is the sole FTF and eligible for 180 days exclusivity. Zydus can launch on Mar 01, 2038.
5.	Mekinist 0.5 mg and 2 mg ; Tablet	Trametinib	None	Novugen	1 st	Total US sales - \$ 791m. Novugen is the only FTF and Para IV filer and will be likely eligible for 180 days exclusivity. Litigation is

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						ongoing. Novugen cannot launch before Nov 2027 (Compound Patent).
6.	Soriatane 17.5mg Capsule	Acitretin	None	Alembic	4 th	All patents have expired. All generic companies have already launched their generic product. Other strengths of this NDA are already genericized.
7.	Opsumit 10 mg; Tablet, Oral	Macitentan	None	Torrent	1 st	Total US sales - \$ 1147. There are 13 Para IV filers. Litigation is settled with most of Para IV filers. Litigation is Partially Settled with Torrent. Zydus, Mylan, Seasons Biotech can launch On Dec 05, 2025 under shared 180 days exclusivity. Others including Torrent can launch after 180 days.
8.	Sprycel 20, 50, 70, 100 mg; Tablet	Dasatinib	None	Apotex	1 st	Total US sales - \$ 1446m. There are 9 Para IV filers. Apotex is the sole FTF. Litigation is settled with all including Apotex. According to settlement Apotex and other multiple generics will launch their product in Sept 2024.
9.	Fintepla 2.2 mg/mL ; Solution	Fenfluramine Hydrochloride	Controlled Substance	Apotex	1 st	Total US sales - \$ 221m. There are two Para IV filers. Litigation is Partially dismissed in favor of generics. Lupin can launch Between Jan 2024 and Aug 2037.

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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	Total US sales - \$ 42m. There are two Para IV filers. Litigation is settled with both including Dr Reddy's. Actavis can launch anytime its generic and Dr Reddy's can launch Between Oct 2025 (Regulatory stay) and Aug 2027.
2.	Invokana 100,300 mg; Tablet, Oral	Canagliflozin	None	Macleods	-	Total US sales - \$ 193m. There are 12 Para IV filers. Litigation is settled with. Multiple FTFs are likely to launch under shared 180 days exclusivity Between Jul 2027 and Feb 2029. Macleods can launch after 180 days.
3.	Edarbyclor 40 mg/12.5 mg and 40 mg/25 mg ; Tablet	Azilsartan Medoxomil and Chlorthalidone	None	Teva	-	There are three Para IV filers. Litigation is settled with Teva. Litigation is ongoing with others. Teva can launch between Feb 2026 and Jul 2031.
4.	Briviact 10 mg/ml; Solution, Oral	Brivaracetam	Controlled Substance	Hainan Poly	-	There are two Para IV filers. Both have lost litigation in DC. MSN (FTF) has appealed in FC. Hainan Poly is not litigated. We assume they might have filed Para III. Generic entry is possible On Feb 21, 2026.

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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	All Patents expired. Heritage has already launched other generic strength. Heritage can launch 250mg anytime.
2.	Dolobid 375mg Tablet SUITABILITY PETITION	Diflunisal	None	Heritage Pharma	1 st	All Patents expired. Heritage can launch anytime.
3.	Pradaxa 110mg Capsule	Dabigatran Etexilate Mesylate	None	Hetero	4 th	There are 7 Para IV filers. Litigation is settled with 3 including Hetero. Apotex, Alembic and MSN have already launched their generics. Hetero can launch anytime.
4.	Brilinta 90mg Tablet	Ticagrelor	None	Prinston Pharma	3 rd	Total US sales - \$744m. There are 23 Para IV filers. Litigation is settled with all. Hec, Hisun and Sandoz are eligible for shared 180 days exclusivity. They can launch between Apr 2025 and Jul 2036. All others including Prinston Pharma can launch after 180 days exclusivity.
5.	Midazolam in 0.9% Sodium Chloride 50 mg/50 mL and 100 mg/100 mL ; Intravenous	Midazolam	Controlled Substances	Gland Pharma	2 nd	There is only 1 Para IV filers. Litigation is ongoing with Hikma. Hikma has launched at risk in 2023. Gland Pharma is not litigated.

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						So, we assume they would have filed Para III. They can launch in Jun 2038.
6.	Bepreve 1.5% ; Solution/Drops, Ophthalmic	Bepotastine Besilate	None	Somerset	4 th	There are 5 Para IV filers. Litigation is Settled with 4. Alembic, Microlabs and Apotex have already launched their generic. Somerset is not litigated. Somerset can launch on Sept 05, 2024 (last patent).
7.	Tranexamic Acid 1gm/100ml (10mg/ml) Intravenous Solution	Tranexamic Acid	None	Fresenius Kabi	4 th	All patents have expired. Other three companies have already launched their generics. Fresenius can launch anytime.
8.	Naropin 5mg/ml Solution, Injection	Ropivacaine Hydrochloride	None	Hikma	3 rd	There are multiple Para IV filers. Other strengths of this product are already genericized. Other companies have already launched 5mg/ml. Hikma can launch anytime.
9.	Tykerb Eq 250mg Base Tablet	Lapatinib Ditosylate	None	Teva	2 nd	Total US sales - \$112m. Natco was the sole FTF and was not litigated. Natco launched its generic in Sept 2020. Teva is not litigated. So, we assume Teva can launch anytime.
10.	Colestid 1gm Tablet	Colestipol Hydrochloride	Polymeric Compounds	Edenbridge Pharms	4 th	All patents have expired. Other three companies have already launched their generic. Edenbridge can launch anytime.

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Tentative Approvals

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1.	Briviact 25, 50, 75, 100 mg Tablet	Brivaracetam	Controlled Substances	Zhejiang	2	Total US sales - \$ 278m. There are 7 FTFs. Litigation is either lost or settled with most. FTFs are likely launch under shared 180 days exclusivity between Feb 2026 and Apr 2030. Zhejiang is not litigated. They can launch after 180 days exclusivity.
2.	SYNJARDY 5mg;500mg/1gm, 12.5mg;500mg/1gm, Tablet	Empagliflozin and Metformin HCL	None	Macleods	-	Total US sales - \$ 400m. There are four FTFs including Macleods. Litigation is settled after losing in DC with Macleods. FTFs are likely to launch with shared 180 days exclusivity between Aug 2028 and Apr 2034.
3.	Lumify (OTC) 0.025% Ophthalmic Solution	Brimondinie Tartrate	None	Lupin	1	There are two Para IV filers. Slayback is FTF and litigation is ongoing. Lupin has settled litigation. Lupin can likely launch between Aug 2024 and Jul 2030.

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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	Total US sales - \$ 115m. There are three Para IV filers. Litigation is settled with all. Sun (Taro) was FTF and launched its generic in Oct 2023 with 180 days exclusivity. Padagis can launch anytime.
2.	Tepadina 15 mg/vial Powder; Intracavitary, Intravenous, Intravesical	Thiotepa	None	Beloteca	4 th	All patents have expired. Other three companies have already launched their generics. Beloteca can launch anytime.
3.	Lucemyra Eq 0.18 mg Base Tablet	Lofexidine Hydrochloride	None	Indoco	1 st	All patents have expired. Indoco has launched its generic under 180 days of CGT Exclusivitys .
4.	Asacol HD 800mg ; Tablet, Delayed Release;Oral	Mesalamine	Targeted Orals , Controlled Substances	Teva	2 nd	Total US sales - \$ 693m. All patents have expired. Zydus and Teva have already launched their generics.
5.	Luxiq 0.12% Aerosol, Foam; Topical	Betamethasone Valerate	None	Alembic	4 th	All patents have expired. All four companies have already launched their generics.
6.	Tiglutik Kit 50 mg/10 mL; Oral Suspension	Riluzole	None	Alkem	1 st	Last patent expires on Mar 12, 2029. Alkem is not litigated. We assume they have filed Para IV and can launch its generic anytime.

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Tentative Approvals

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1.	Vyndamax 61mg; Capsule	Tafamidis	None	Zenara Pharma	-	There are three FTFs. Litigation is ongoing with all three including Zenara Pharma. All FTF are likely eligible for shared 180 days exclusivity. Generic launch is not possible before Nov 2026 (Regulatory Stay).

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