

# LOW COMPETITION APPROVALS THIS MONTH

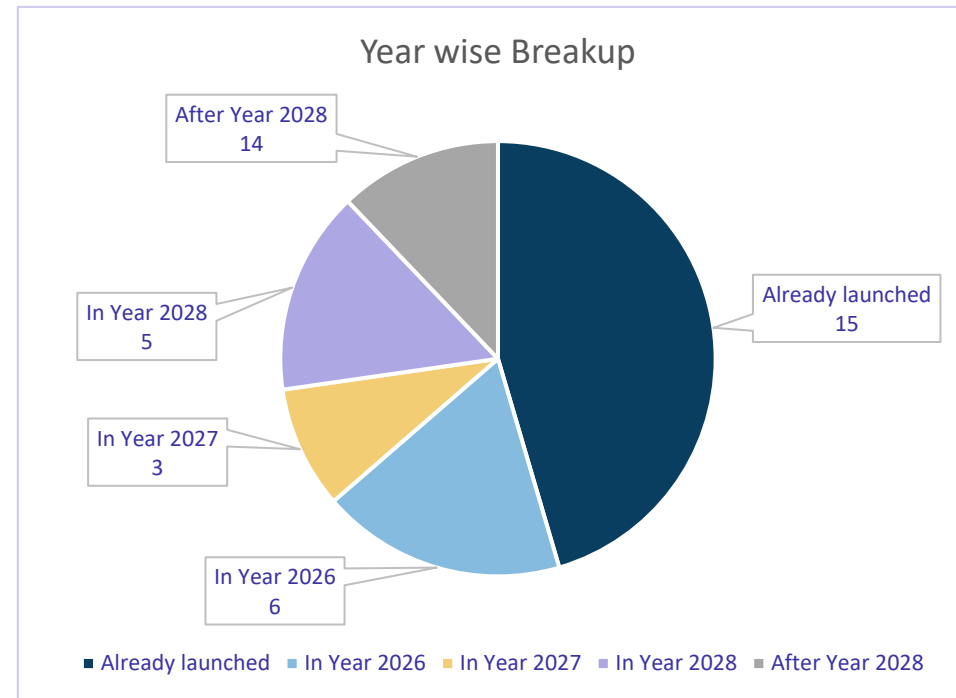
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COMBINED REPORT FOR APRIL 2026

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## Quick Insights for Loss of Exclusivity in Upcoming Year



Source – GenUS and Para IV Database

**Research Delta Advisors**

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

# LOW COMPETITION APPROVALS



02<sup>ND</sup> APR – 08<sup>TH</sup> APR, 2026

## Final Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>1</sup>
1.	Xigduo XR (Astrazeneca)	Dapagliflozin; Metformin hydrochloride 5,10 mg/500mg; 5,10 mg/1000 mg Tablets, Extended release	Macleods	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Ofev (Boehringer Ingelheim)	Nintedanib 150 mg Capsule	Sandoz (Lotus Pharma), Dr Reddy's, Dexcel Pharma	1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Qtern (Astrazeneca)	Dapagliflozin and Saxagliptan 10 mg/5 mg; Tablet	MSN, Torrent	1 <sup>st</sup> , 2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>

<sup>1</sup> Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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<b>PREMIUM CONTENT</b>							
4.	Qbrexza Journey Medical (Erstwhile Dermira)	Glycopyrronium Tosylate 2.4 %, Topical Cloth	Padagis (Perrigo)	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
5.	Rowasa (Mylan)	Mesalamine 4gm/60ml Enema; Rectal	KLM Labs	4 <sup>th</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

There are no Low competition Tentative Approvals This week

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# LOW COMPETITION APPROVALS



09<sup>TH</sup> APR – 15<sup>TH</sup> APR, 2026

## Final Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>2</sup>
1.	Xigduo XR (Astrazeneca)	Dapagliflozin; Metformin hydrochloride 2.5 mg/1000 mg; Tablet ER	Teva	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Infuvite Adult (Sandoz)	Alpha-Tocopherol Acetate; Ascorbic Acid; Biotin; Cholecalciferol; Cyanocobalamin; Dexpanthenol; Folic Acid; Niacinamide; Pyridoxine Hydrochloride; Riboflavin 5'-Phosphate Sodium; Thiamine Hydrochloride; Vitamin A Palmitate; Vitamin K (2 Iu/MI;40mg/ml;12mcg/ml; 40 Iu/MI;1mcg/ml; 3mg/ml;120mcg/ml;8mg/ml 1.2mg/ml;0.72mg/ml;1.2mg/ml; 660 Iu/ml;0.03mg/ml)	Apotex	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>

<sup>2</sup> Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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		(2 lu/ml;40mg/ml;12mcg/ml; 40 lu/ml;1mcg/ml;3mg/ml; 120mcg/ml; 8mg/ml;1.2mg/ml; 0.72mg/ml;1.2mg/ml; 660 lu/ml;30mcg/ml)  Solution; Intravenous					
<b>PREMIUM CONTENT</b>							
3.	Endometrin (Ferring)	Progesterone 100mg Insert; Vaginal	Glenmark	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Descovy (Gilead)	Emtricitabine and Tenofovir Alafenamide Fumarate 200mg/ 25mg; Tablet	Macleods	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
5.	Catapres (Boehringer Ingelheim)	Clonidine Hydrochloride <b>Suitability Petition</b> 0.05 mg Tablet	TP Anda Holdings	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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# LOW COMPETITION APPROVALS



## Tentative Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>1</sup>
1.	Firdapse (Catalyst Pharma)	Amifampridine Phosphate 10 mg Tablet	Inventia	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Nexletol (Esperion Theraps)	Bempedoic Acid 180 mg Tablet	Renata	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Xtandi (Astellas)	Enzalutamide 40 mg Capsule	Ascent	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Gemtesa (Urovant)	Vibegron 75 mg Tablet	Apotex	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
5.	Verquvo (MSD)	Vericiguat 2.5 mg; Tablet	Changzhou Pharma	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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6.	Verquvo (MSD)	Vericiguat 5 and 10 mg Tablet	Changzhou Pharma	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
7.	Ozempic (Novo Nordisk)	Semaglutide 2 mg/1.5 ml and 4 mg/3 ml Solution, Subcutaneous	Apotex (Orbicular)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
8.	Ozempic (Novo Nordisk)	Semaglutide 8 mg/ 3 ml; Solution, Subcutaneous	Apotex (Orbicular)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
9.	Ozempic (Novo Nordisk)	Semaglutide 2 mg/3 ml Solution, Subcutaneous	Apotex (Orbicular)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
10.	Triumeq PD (VIIV Healthcare)	Abacavir Sulfate, Dolutegravir and Lamivudine 60mg/5mg/30mg Tablet for Suspension	Microlabs	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

<sup>2</sup> Probable Generic 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



16<sup>TH</sup> APR – 22<sup>ND</sup> APR, 2026

## Final Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>3</sup>
1.	Orap (Teva)	Pimozide 1mg and 2 mg Tablet	Novitium Pharm (Ani Pharma)	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Ravicti (Horizon Pharma)	Glycerol Phenylbutyrate 1.1 gm/ml Liquid, Oral	Aurobindo, MSN, Teva	2 <sup>nd</sup> , 3 <sup>rd</sup> , 4 <sup>th</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Invokana (Janssen Pharma)	Canagliflozin 100,300 mg Tablet, Oral	Aurobindo, Apotex	1 <sup>st</sup> , 2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Delsym (RB Health)	Dextromethorphan Polistirex 30 mg Hydrobromide/5ml Suspension Extended Release, Oral	Aurobindo	3 <sup>rd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>

<sup>3</sup> Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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<b>PREMIUM CONTENT</b>							
5.	Retin-A Micro (Bausch)	Tretinoin 0.06% Gel, Topical	Encube	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
6.	Uptravi (Actelion Pharmaceuticals)	Selexipag 0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.6 mg Tablet	RK Pharma (Aizant)	1 <sup>st</sup> , 2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

## Tentative Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>1</sup>
1.	Dojolvi (Ultragenyx)	Triheptanoin 100% w/w Oral, Liquid	Navinta	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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# LOW COMPETITION APPROVALS



23<sup>RD</sup> APR – 29<sup>TH</sup> APR, 2026

## Final Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>4</sup>
1.	Infuvite Pediatric & Pharmacy Bulk Package (Sandoz)	Ascorbic Acid; Biotin; Cholecalciferol; Cyanocobalamin; Dexpanthenol; Folic Acid; Niacinamide; Pyridoxine; Riboflavin; Thiamine; Tocopherol Acetate; Vitamin A; Vitamin K  80mg/Vial;0.02mg/Vial;400 lu/Vial;0.001mg/Vial; 5mg/Vial;0.14mg/Vial;17mg/Vial; 1mg/Vial; 1.4mg/Vial;1.2mg/Vial;7 lu/Vial;2,300 lu/Vial; 0.2mg/Vial  Injectable; Intravenous	Apotex (Orbicular)	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Xtandi (Astellas)	Enzalutamide 40 mg, 80 mg Tablets	Sandoz	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>

<sup>4</sup> Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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<b>PREMIUM CONTENT</b>							
3.	Jynarque (Otsuka)	Tolvaptan 15 mg, 30 mg, 45 mg and 60 mg Tablets	Alkem	3 <sup>rd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Symbicort (Astrazeneca)	Budesonide; Formoterol Fumarate dihydrate 0.08,0.16mg/inh; 0.0045mg/inh, Aerosol, Metered	Teva	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
5.	Ventolin HFA (Glaxosmithkline)	Albuterol Sulfate Eq 0.09mg Base/Inh Aerosol, Metered; Inhalation	Cipla	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
6.	Monoket (Omnivium Pharms)	Isosorbide Mononitrate 10 Mg Tablets	ANI Pharms	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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1.	Verquvo (MSD)	Vericiguat 2.5 mg; Tablet	Torrent	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Verquvo (MSD)	Vericiguat 5 and 10 mg Tablet	Torrent	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

<sup>1</sup>Probable Generic 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



30<sup>TH</sup> APR – 06<sup>TH</sup> MAY, 2026

## Final Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>5</sup>
1.	Buspar (Bristol Myers Squibb)	Buspiron Hydrochloride 5 mg Capsule	Epic Pharma	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Ak-Fluor 10% (Long Grove Pharms)	Fluorescein Sodium Eq 500mg Base/5ml Injectable; Intravenous	BPI Labs	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Janumet (Merck)	Metformin Hydrochloride; Sitagliptin Phosphate 500mg;50mg, 1gm;50mg Tablet	Apotex	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Zonalon (Mylan)	Doxepin Hydrochloride 5% Cream; Topical	Sun Pharma	3 <sup>rd</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>

<sup>5</sup> Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

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<b>PREMIUM CONTENT</b>							

## Tentative Approvals

Sr. No	Brand Name & (Owner)	Generic Name, Strength & Dosage	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers <sup>1</sup>
1.	Xcopri (SK Life)	Cenobamate 12.5, 25, 50, 100, 150 and 200 mg Tablet	Aurobindo	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Qelbree (Supernus Pharms)	Viloxazine Hydrochloride 150 mg Extended-Release Capsules	Somerset (Appco)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Qelbree (Supernus Pharms)	Viloxazine Hydrochloride 100 mg	Somerset (Appco)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>

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		Extended-Release Capsules					
<b>PREMIUM CONTENT</b>							
4.	Qelbree (Supernus Pharms)	Viloxazine Hydrochloride 200 mg Extended-Release Capsules	Somerset (Appco)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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