

# LOW COMPETITION APPROVALS THIS MONTH

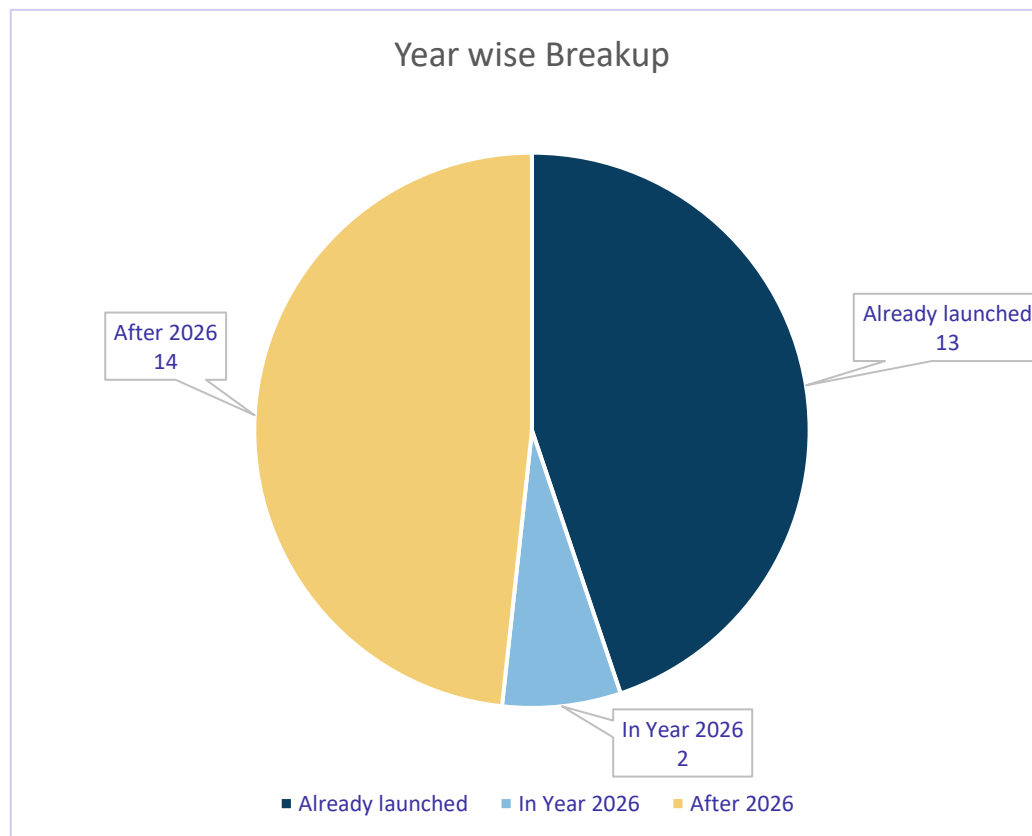
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COMBINED REPORT FOR MAY 2026

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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



07<sup>th</sup> MAY – 13<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>1</sup>
1.	Calcium Gluconate (Fresenius Kabi)	Calcium Gluconate 1gm/10ml (100mg/ml), 5gm/50ml (100mg/ml) Solution; Intravenous	Caplin	3 <sup>rd</sup> , 4 <sup>th</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Solu-Cortef (Pharmacia And Upjohn)	Hydrocortisone Sodium Succinate Eq 100mg Base/Vial Injectable; Injection	Zydus	3 <sup>rd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Vasostriect (Par Pharma)	Vasopressin 200 units/10 mL Solution, Intravenous	Sandoz	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

There are no low competition tentative approvals this week

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

### Research Delta Advisors

# LOW COMPETITION APPROVALS



14<sup>th</sup> MAY – 20<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>2</sup>
1.	Estrogel (Ascend Theraps)	Estradiol 0.06% (1.25gm/Activation) Gel, Metered; Transdermal	Encube	4 <sup>th</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Zolpidem Tartrate (Almatica)	Zolpidem Tartrate 7.5 mg Capsule	Umedica	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Retin-A Micro (Bausch)	Tretinoin 0.08% Gel, Topical	Amneal	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	Yes	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Venclexta (AbbVie)	Venetoclax (10 mg, 50 mg and 100 mg)	Dr Reddys	1 <sup>st</sup>	<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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5.	Endari (Emmaus Medcl)	L-Glutamine 5gm/Packet For Solution: Oral	Stira	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
6.	Neurontin (Viatris)	Gabapentin Suitability Petitions 200mg Capsule; Oral	Senores Pharms	2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
7.	Suprax (Lederle)	Cefixime 100mg/5ml For Suspension; Oral	FDC Ltd	4 <sup>th</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>2</sup>
1.	Janumet (Merck)	Metformin Hydrochloride; Sitagliptin Phosphate 500mg;50mg, 1gm;50mg Tablet	Inventia	2	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Sutab (Braintree Laboratories)	Sodium Sulfate, Magnesium Sulfate and Potassium Chloride 1.479 g/ 0.225 g/ 0.188 g Tablet	Hetero	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Ubrelyv (AbbVie)	Ubrogepant 50 and 100 mg Tablet	Zydus	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Nexlizet (Esperion Therapies Inc)	Bempedoic Acid and Ezetimibe 180 mg/10 mg; Tablet	Sandoz	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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5.	Fotivda (Aveo Pharmaceuticals)	Tivozanib Hydrochloride 0.89 and 1.34 mg Capsules	Sandoz (Hetero)	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
6.	Nubeqa (Bayer)	Darolutamide 300 mg Tablet	Alembic	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
7.	Kerendia (Bayer)	Finerenone 10 mg and 20 mg Tablet	Macleods	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



21<sup>st</sup> MAY – 27<sup>th</sup> MAY, 2026

There are no final approvals this week

## 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>3</sup>
1.	Jardiance (Boehringer Ingelheim)	Empagliflozin 10, 25 mg <a href="#">Suitability Petition</a> 2.5 mg Tablet, Oral	Aurobindo	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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2.	Yupelri (Viatris (Mylan)- Theravance)	Revefenacin 175 mcg/3 mL; Inhalation Solution	Lupin	None	<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	Mankind Pharma	2	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
4.	Calquence (AstraZeneca)	Acalabrutinib Maleate Eq 100 mg Base Tablet	MSN Labs	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
5.	Ibrance (Pfizer)	Palbociclib 75, 100, 125 mg Tablet	Dr Reddy's	None	<b>PREMIUM CONTENT</b>		<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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# LOW COMPETITION APPROVALS



28<sup>th</sup> MAY – 03<sup>rd</sup> JUN, 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.	Endari (Emmaus Medcl)	L-Glutamine 5gm/Package For Solution: Oral	Annora Pharma	3 <sup>rd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Sutab (Braintree Laboratories)	Sodium Sulfate, Magnesium Sulfate and Potassium Chloride 1.479 g/ 0.225 g/ 0.188 g Tablet	Lupin	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Epinephrine BPI Labs	Epinephrine 1mg/ml (1mg/ml) Solution; Intramuscular, Intravenous, Subcutaneous	Hikma	1 <sup>st</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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4.	Ak-Fluor 10%, Ak-Fluor 25% (Long Grove Pharms)	Fluorescein Sodium Eq 500mg Base/5ml (Eq 100mg Base/ml), Eq 500mg Base/2ml (Eq 250mg Base/ml) Injectable; Intravenous	Zydus	3 <sup>rd</sup> , 2 <sup>nd</sup>	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							

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1.	Orgovyx (Sumitomo Dainippon)	Relugolix 120 mg; Tablet	Hetero	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
2.	Dificid Cubist (Merck)	Fidaxomicin 200 mg Tablets	Sandoz	3	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<b>PREMIUM CONTENT</b>							
3.	Welireg (Merck)	Belzutifan 40mg; Tablet	Zydus	None	<b>PREMIUM CONTENT</b>	No	<b>PREMIUM CONTENT</b>
<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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