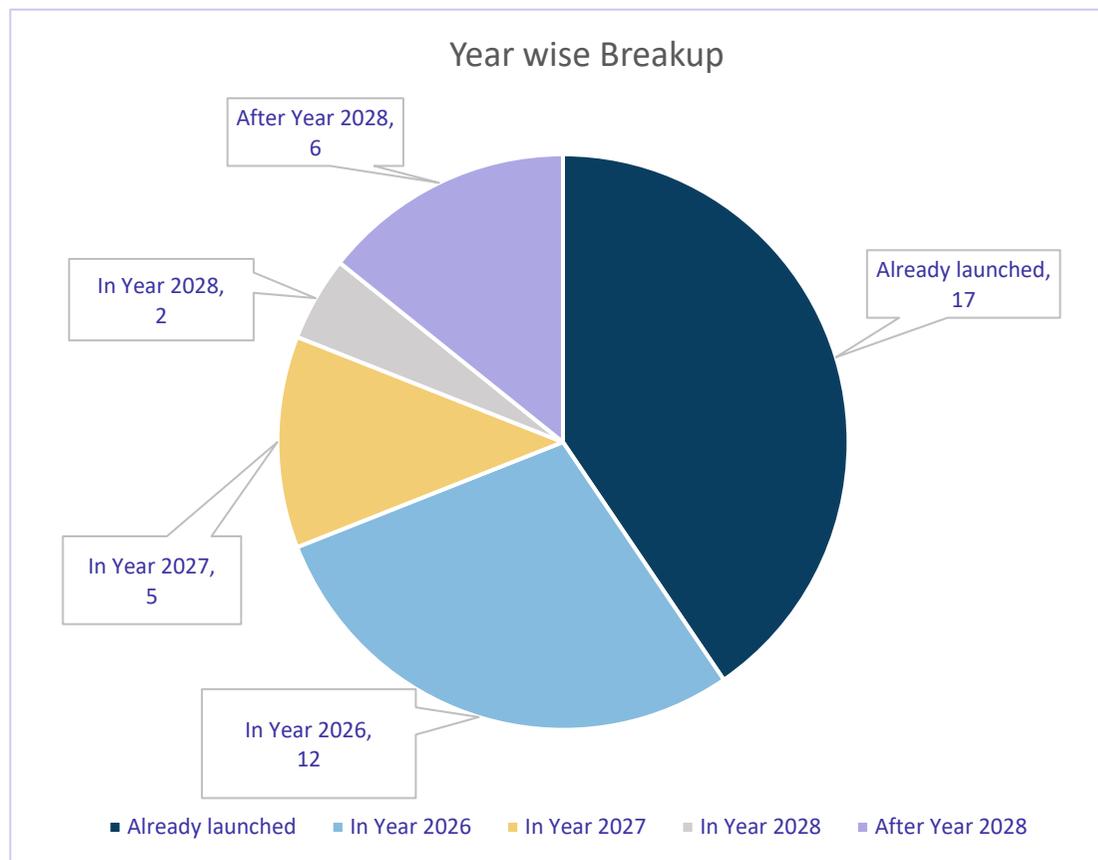


LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR FEBRUARY 2026



Quick Insights for Loss of Exclusivity in Upcoming Year



Source – GenUS and Para IV Data base

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LOW COMPETITION APPROVALS



29TH JAN – 04TH FEB, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ¹
1.	Cupric Chloride in Plastic Container Eq 0.4mg Copper/ml Injectable; Injection	Cupric Chloride	Amneal	4 th	PREMIUM CONTENT	No	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Nucynta 50,75,100 mg Tablets	Tapentadol Hydrochloride	Humanwell	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Dificid 200 mg Tablets	Fidaxomicin	Torrent	2 nd	PREMIUM CONTENT	No	PREMIUM CONTENT
	PREMIUM CONTENT						
4.	Lymphazurin <u>Suitability Petition</u> 10mg/ml (10mg/ml),	Isosulfan Blue	Mylan Institutional	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT

¹ 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



Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ¹
	30mg/3ml (10mg/ml) Solution; Subcutaneous						
PREMIUM CONTENT							
5.	Edurant 25mg Tablet	Rilpivirine	Somerset	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
6.	Odefsey 200mg; Eq 25mg Base;Eq 25mg Base Tablet	Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Alafenamide Fumarate	Apotex	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
7.	Estrogel 0.06% (1.25gm/Activation) Gel, Metered; Transdermal	Estradiol	Long Grove Pharmaceuticals	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							

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LOW COMPETITION APPROVALS



Tentative Approvals

Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ¹
1.	Trintellix 5,10,15,20 mg Tablets	Vortioxetine	Apotex	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
2.	Januvia 25, 50 and 100 mg Tablets	Sitagliptin Phosphate	Fosun Wanbang (Jiangsu) Pharmaceutical	3	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
3.	Xigduo XR 5,10 mg/500mg; 5,10 mg/1000 mg Tablets, Extended release	Dapagliflozin; Metformin hydrochloride	Inventia	None	PREMIUM CONTENT	Yes	PREMIUM CONTENT
PREMIUM CONTENT							
4.	Xigduo XR 2.5 mg/1000 mg	Dapagliflozin; Metformin hydrochloride	Inventia	None	PREMIUM CONTENT	Yes	PREMIUM CONTENT

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LOW COMPETITION APPROVALS



Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ¹
	Tablets, Extended release						
PREMIUM CONTENT							
5.	Erleada 60 mg Tablets	Apalutamide	Hetero	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
6.	Erleada 240 mg Tablets	Apalutamide	Hetero	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							

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LOW COMPETITION APPROVALS



05TH FEB – 11TH FEB, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ²
1.	Topamax Sprinkle 50mg Capsules	Topiramate	Strides Pharma	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Dificid 200 mg Tablets	Fidaxomicin	Apotex	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Stalevo 100, Stalevo 150, Stalevo 125, Stalevo 200, Stalevo 50, Stalevo 75 12.5mg;200mg;50mg, 18.75mg;200mg;75mg, 25mg;200mg;100mg, 31.25mg;200mg;125mg,	Carbidopa; Entacapone; Levodopa	Alembic	3 rd	PREMIUM CONTENT	Yes	PREMIUM CONTENT

² 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



Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ²
	37.5mg;200mg;150mg, 50mg;200mg;200mg Tablets						
PREMIUM CONTENT							
4.	Solu-Cortef Eq 100mg Base/Vial Injectable; Injection	Hydrocortisone Sodium Succinate	Apotex	2 nd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
5.	Azactam 1gm/Vial, 2gm/Vial Injectable; Injection	Aztreonam	Hikma	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
6.	Glucotrol Suitability Petition 15mg Tablets	Glipizide	Rubicon Research	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
7.	Provayblue 5mg/ml (5mg/ml) Suitability Petition Solution; Intravenous	Methylene Blue	Zydus	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
8.	Zoledronic Acid Eq 4mg Base/100ml Injectable; Intravenous	Zoledronic Acid	Gland pharma	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT

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LOW COMPETITION APPROVALS



Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ²
PREMIUM CONTENT							

Tentative Approvals

Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ²
1.	Sunosi 75, 150 mg Suitability Petition (300 mg) Tablets	Solriamfetol Hydrochloride	Aurobindo	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
2.	Xtandi 40 mg, 80 mg Tablets	Enzalutamide	Hikma	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							

² 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



12TH FEB – 18TH FEB, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Approved Company Name	No. Of Final Approvals	Para IV Filers To Be Approved	Innovator has Authorized Generics?	Probable Generic Developers ³
1.	Glucophage 625mg, 750mg Tablets	Metformin Hydrochloride	Sciegen Pharms	2 nd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
2.	Nucynta 50,75,100 mg Tablets	Tapentadol Hydrochloride	Hikma	2 nd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
3.	FML 0.1% Suspension/Drops Ophthalmic	Fluorometholone	Difgen Pharms	2 nd	PREMIUM CONTENT	Yes	PREMIUM CONTENT
PREMIUM CONTENT							

There are no Low Competition Tentative Approvals this week.

³ 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



19TH FEB – 25TH FEB, 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 ⁴
1.	Lac-Hydrin Sun Pharma (Erstwhile Bristol-Myers)	Ammonium Lactate Eq 12% Base Cream; Topical	Zydus	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
2.	Buphenyl Horizon Therap US	Sodium Phenylbutyrate 500mg Tablets	Navinta LLC	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
3.	Zydelig Gilead Sciences	Idelalisib 100mg, 150 mg Tablets	Natco	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
4.	Tracleer Actelion pharmaceuticals	Bosentan 32 mg; Tablet for suspension, Oral	Zydus	2 nd	PREMIUM CONTENT	No	PREMIUM CONTENT

⁴ 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



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 ⁴
PREMIUM CONTENT							
5.	Atrovent HFA Boehringer Ingelheim	Ipratropium Bromide 0.21 mg/Inh; Inhalation Aerosol	Armstrong Pharms	1 st	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
6.	Briviact UCB pharma	Brivaracetam 50 mg/5 ml; Solution, Intravenous	Hainan Poly	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							

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 ⁴
1.	Nayzilam UCB pharma	Midazolam 5 mg nasal spray	Padagis	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							

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LOW COMPETITION APPROVALS



26TH FEB – 04TH MAR, 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 ⁵
1.	Jublia Bausch Health (Erstwhile Valeant)	Efinaconazole 10% Topical, Solution	Aleor (Alembic + Orbicular)	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
2.	Saxenda Novo Nordisk	Liraglutide 18mg/3ml (6mg/ml)	Orbicular, Biocon	2 nd , 3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
3.	Dalvance Abbvie	Dalbavancin Hydrochloride Eq 500mg base/vial Powder; Intravenous	Long Grove Pharms	4 th	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
4.	Sodium Phosphates in Plastic Container Hospira	Sodium Phosphate, Dibasic, Heptahydrate;	Caplin	3 rd	PREMIUM CONTENT	No	PREMIUM CONTENT

⁵ 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



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 ⁵
		Sodium Phosphate, Monobasic, Monohydrate					
PREMIUM CONTENT							

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 ⁵
1.	Ibrance Pfizer	Palbociclib 75, 100, 125 mg; Capsule, Oral	Cipla	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
2.	Janumet Merck	Metformin Hydrochloride; Sitagliptin Phosphate 500mg;50mg, 1gm;50mg Tablet	Aurobindo	1	PREMIUM CONTENT	No	PREMIUM CONTENT

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LOW COMPETITION 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 ⁵
PREMIUM CONTENT							
3.	Alecensa Roche	Alectinib 150 mg; Capsule, Oral	Natco	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
4.	Sutab Braintree Laboratories	Sodium Sulfate, Magnesium Sulfate and Potassium Chloride	Somerset (Appco)	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							
5.	Synjardy XR Boehringer Ingelheim	Empagliflozin; Metformin Hydrochloride 10,12.5,25 mg/1 gm, Tablet, Extended Release	Ajanta	None	PREMIUM CONTENT	No	PREMIUM CONTENT
PREMIUM CONTENT							

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

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