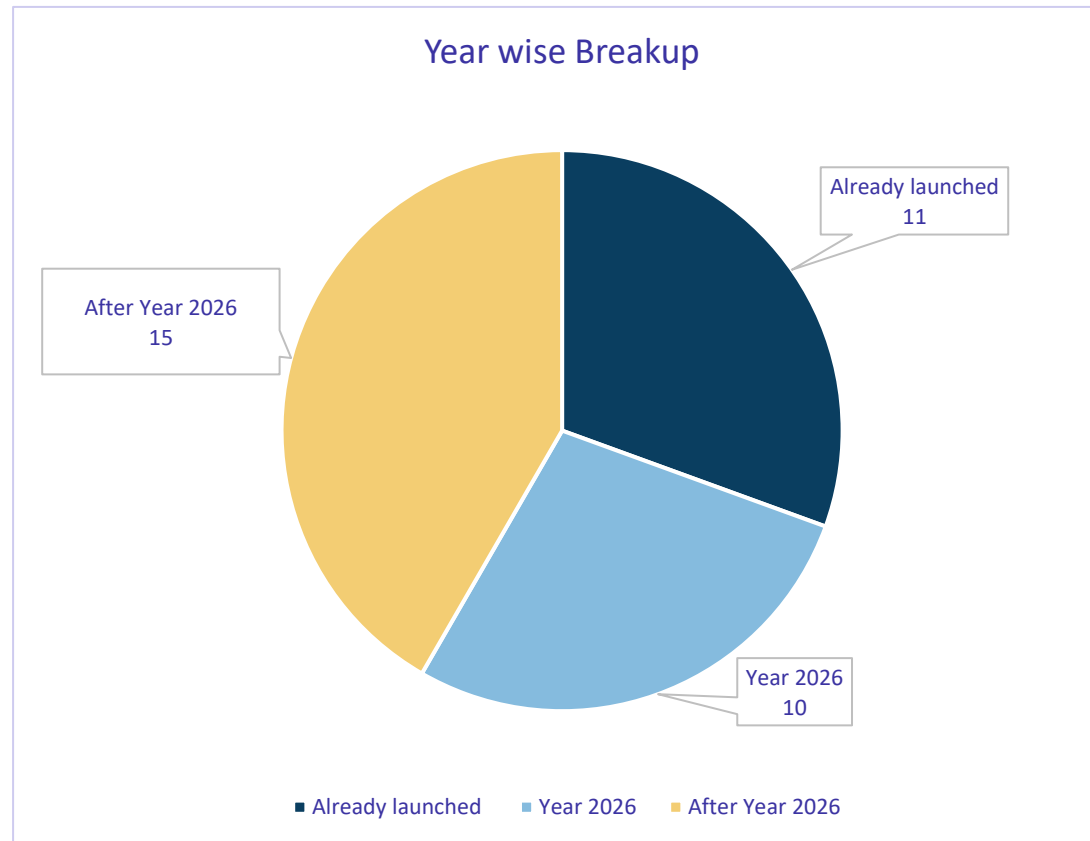


LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR JANUARY 2026



Quick Insights for Loss of Exclusivity in Upcoming Year



Source – GenUS and Para IV Data base

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LOW COMPETITION APPROVALS



01ST JAN – 07TH JAN, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Probable Generic Developers ¹
1.	Calcium Gluconate in Sodium Chloride 1gm/50ml (20mg/ml) 2gm/100ml (20mg/ml) Solution; Intravenous	Calcium Gluconate	PREMIUM CONTENT	Sagent	2 nd	PREMIUM CONTENT
	PREMIUM CONTENT					
2.	Selenious Acid Eq 60mcg Selenium/ml Solution, Intravenous	Selenious Acid	PREMIUM CONTENT	RK Pharma	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
3.	Januvia 25, 50 and 100 mg Tablet	Sitagliptin Phosphate	PREMIUM CONTENT	Watson	1 st	PREMIUM CONTENT
	PREMIUM CONTENT					
4.	Velettri Eq 0.5mg Base/Vial, Eq 1.5mg Base/Vial	Epoprostenol Sodium	PREMIUM CONTENT	Gland Pharma	3 rd	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	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Probable Generic Developers ¹
	Injectable, Injection					
	PREMIUM CONTENT					

There are no Low Competition Tentative Approvals this week

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LOW COMPETITION APPROVALS



08TH JAN – 14TH JAN, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ²
1.	Magnesium Sulfate in Plastic Container Suitability Petition 3gm/100ml (30mg/ml) Injectable; Injection	Magnesium Sulfate	PREMIUM CONTENT	Baxter	1 st	No	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Advair Diskus 100/50, Advair Diskus 250/50 0.1mg/Inh; Eq 0.05mg Base/Inh 0.25mg/Inh; Eq 0.05mg Base/Inh Powder; Inhalation	Fluticasone Propionate; Salmeterol Xinafoate	PREMIUM CONTENT	Respirent Pharms	4 th	Yes	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Afinitor Disperz 2mg, 3mg, 5mg	Everolimus	PREMIUM CONTENT	Biocon	3 rd	No	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	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ²
	Tablet, For Suspension						
	PREMIUM CONTENT						

Tentative Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ²
1.	Adzenys XR- ODT 3.1,6.3,9.4,12.5,15.7,18.8 mg Tablet Extended	Amphetamine	PREMIUM CONTENT	Granules	1	Yes	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Eliquis 2.5, 5 mg; Tablet, Oral	Apixaban	PREMIUM CONTENT	Fosun Wanbang (Jiangsu) Pharmaceutical	3	No	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Farxiga 5,10 mg Tablet	Dapagliflozin	PREMIUM CONTENT	Sciegen	None	Yes	PREMIUM CONTENT

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LOW COMPETITION APPROVALS



Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ²
	PREMIUM CONTENT						
4.	Ravicti 1.1 gm/ml Liquid, Oral	Glycerol Phenylbutyrate	PREMIUM CONTENT	Aurobindo	1	No	PREMIUM CONTENT
	PREMIUM CONTENT						
5.	Reyvow 50 and 100 mg Tablet	Lasmiditan Succinate	PREMIUM CONTENT	Humanwell	None	No	PREMIUM CONTENT
	PREMIUM CONTENT						
6.	Ofev 100 mg and 150 mg Suitability Petition 25 mg Capsule	Nintedanib	PREMIUM CONTENT	Apotex, Humanwell	None	No	PREMIUM CONTENT
	PREMIUM CONTENT						
7.	Xifaxan 550 mg Tablet	Rifaximin	PREMIUM CONTENT	Mylan	None	No	PREMIUM CONTENT
	PREMIUM CONTENT						
8.	Xifaxan 200 mg Tablet	Rifaximin	PREMIUM CONTENT	Mylan	None	No	PREMIUM CONTENT

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LOW COMPETITION APPROVALS



Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ²
	PREMIUM CONTENT						
9.	Nurtec ODT 75 mg Orally Disintegrating Tablets	Rimegepant	PREMIUM CONTENT	Aurobindo	None	No	PREMIUM CONTENT
	PREMIUM CONTENT						
10.	Selenious Acid Eq 60mcg Selenium/ml; Solution, Intravenous	Selenious Acid	PREMIUM CONTENT	BPI Labs	1	No	PREMIUM CONTENT
	PREMIUM CONTENT						
11.	Selenious Acid Eq 12mcg Selenium/2ml; Solution, Intravenous	Selenious Acid	PREMIUM CONTENT	BPI Labs	2	No	PREMIUM CONTENT
	PREMIUM CONTENT						
12.	Uptravi 0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.6 mg; Tablet	Selexipag	PREMIUM CONTENT	Lannett	1	No	PREMIUM CONTENT
	PREMIUM CONTENT						
13.	Belsomra 5, 10, 15 and 20 mg Tablet	Suvorexant	PREMIUM CONTENT	Hetero	None	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



15TH JAN – 21ST JAN, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Approved Company Name	Para IV Filers To Be Approved	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ³
1.	Nurtec ODT 75 mg Orally Disintegrating Tablets	Rimegepant Sulfate	Apotex	PREMIUM CONTENT	1 st	No	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Promacta Eq 25mg Acid, Eq 12.5mg 50 mg and 75 mg Tablets Eq 100mg Acid Tablet	Eltrombopag Olamine	Amneal, Somerset, Zydus, MSN	PREMIUM CONTENT	2 nd , 3 rd 4 th , 5 th	No	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Actigall 150 mg Capsule	Ursodiol	Strides Pharma	PREMIUM CONTENT	1 st	Yes	PREMIUM CONTENT

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



Sr. No	Brand Name	Generic Name	Approved Company Name	Para IV Filers To Be Approved	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ³
	PREMIUM CONTENT						
4.	Januvia 25, 50 and 100 mg Tablet	Sitagliptin Phosphate	Sandoz	PREMIUM CONTENT	2 nd	No	PREMIUM CONTENT
	PREMIUM CONTENT						
5.	Victoza 18mg/3ml (6mg/ml) Solution; Subcutaneous	Liraglutide	Orbicular	PREMIUM CONTENT	4 th	Yes	PREMIUM CONTENT
	PREMIUM CONTENT						

There are no Low Competition Tentative Approvals this week.

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LOW COMPETITION APPROVALS



22ND JAN – 28TH JAN, 2026

Final Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ⁴
1.	Januvia 25, 50 and 100 mg Tablet	Sitagliptin Phosphate	PREMIUM CONTENT	Apotex	3 rd	No	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Myrbetriq Granules 8 mg/mL Granules for Extended- release Suspension	Mirabegron	PREMIUM CONTENT	Alkem	1 st	No	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Sertraline Hydrochloride Eq 150mg Base, Eq 200mg Base Capsule	Sertraline Hydrochloride	PREMIUM CONTENT	Umedica, Appco, Novitium Pharma	2 nd , 3 rd , 4 th	No	PREMIUM CONTENT
	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	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ⁴
4.	Nucynta 20mg/ml Oral Solution	Tapentadol Hydrochloride	PREMIUM CONTENT	Novitium	1 st	No	PREMIUM CONTENT
	PREMIUM CONTENT						
5.	Valtoco 10 mg/spray; Nasal Spray	Diazepam	PREMIUM CONTENT	Padagis	1 st	No	PREMIUM CONTENT
	PREMIUM CONTENT						
6.	Valtoco 5 mg/spray and 7.5 mg/spray; Nasal Spray	Diazepam	PREMIUM CONTENT	Padagis	1 st	No	PREMIUM CONTENT
	PREMIUM CONTENT						

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LOW COMPETITION APPROVALS



Tentative Approvals

Sr. No	Brand Name	Generic Name	Para IV Filers To Be Approved	Approved Company Name	No. Of Final Approvals	Innovator has Authorized Generics?	Probable Generic Developers ⁴
1.	Gilotrif 20,30 and 40 mg Tablet	Afatinib	PREMIUM CONTENT	Sandoz	None	No	PREMIUM CONTENT
	PREMIUM CONTENT						
2.	Auryxia EQ 210mg Iron Tablet, Oral	Ferric citrate	PREMIUM CONTENT	Teva	None	Yes	PREMIUM CONTENT
	PREMIUM CONTENT						
3.	Cyclophosphamide 500 mg/2.5 ml and 1 g/5 ml; Solution, Intravenous	Cyclophosphamide	PREMIUM CONTENT	Hetero	1	No	PREMIUM CONTENT
	PREMIUM CONTENT						
4.	Cyclophosphamide 2 g/10 ml; Solution, Intravenous	Cyclophosphamide	PREMIUM CONTENT	Hetero	1	No	PREMIUM CONTENT
	PREMIUM CONTENT						
5.	Nurtec ODT 75 mg Orally Disintegrating Tablets	Rimegepant Sulfate	PREMIUM CONTENT	Rubicon	None	No	PREMIUM CONTENT
	PREMIUM CONTENT						

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