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Mini Review

Dapagliflozin Tablet Patents and Generic Launch: Recent Developments

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ABSTRACT

Dapagliflozin is oral sodium-glucose cotransporter 2 (SGLT2) inhibitor class of antidiabetic agent. It is commercially available as tablet with 5 mg & 10mg under the brand name Farxiga by Astrazeneca. Dapagliflozin is protected by several patents and the same has been listed in US Food and Drug Administration orange book database. The molecule patent expired on April 6, 2026 in United States opens the door for generic players. There are 15 first to filer generic players who launched their generic Dapagliflozin tablet product followed by molecule patent expiration. Therefore, the molecule patent is the main primary barrier for generic players to enter the market before expiration of secondary patents such as polymorph, method of treatment, formulation.

INTRODUCTION

Dapagliflozin is antidiabetic agent belonging to class of sodium-glucose cotransporter 2 (SGLT2) inhibitors, helping the kidneys remove excess glucose and sodium from the body. Dapagliflozin is approved in US & Europe as tablet in two strengths 5mg & 10mg. Type 2 diabetes affects over 40 million Americans, with the vast majority (90–95%) diagnosed with this form of the disease. Expanding access to proven therapies can have a meaningful impact on long-term outcomes [1]. The US Food & Drug administration Dapagliflozin (Farxiga) tablet approval details mentioned in table 01 as below.

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Table 01: Dapagliflozin (Farxiga) tablet US approval details [2-5]

Active ingredient	**Dapagliflozin**		
Brand name & New Drug Application number	Farxiga [N202293]		
Dosage form & strength	Tablet (5mg & 10mg)		
Approval date	Jan 08, 2014		
Innovator	Astrazeneca AB		
Indications & Usage	(i) Chronic kidney disease at risk of progression, (ii) To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure, (iii) To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and (iv) type 2 diabetes mellitus.		
Total Sales	US $ 10.53 billion [MAT Dec 2025]		
Authorized Generic Sale	US $ 738.4 million [MAT Dec 2025]		
Approved generics (First to filers)	**15 FTF ANDA filers received final approved:** Aizant, Ajanta, Alembic, Alkem, Apotex, Aurobindo, Biocon, Bionpharma, Cipla, Glenmark, Hetero, Inventia, Lupin, Macleods, Micro, MSN, Sandoz, Sun Pharma, Teva and Zydus **05 FTF ANDA filers tentatively approved:** Apotex, Bionpharma, Glenmark Generics, Hetero and Sun Pharma		
Other ANDA filers	Jiangsu, ScieGen and Others		
Authorized Generic	Prasco Labs		
Active US Drug Master File holders (USDMF) [4]	**More than 60 Active USDMF holders:** MSN, Dr. Reddys, Lupin, Zydus, Alembic Pharma, Sun Pharma, Biocon, USV and others		
Patent protection – orange book listed patents [5]	There are 11 patents listed in orange book against Farxiga tablet (5mg & 10mg) as on May 12, 2026.		
	Patent No.	**Expiry date**	**Type of patent**
	US6515117	Apr 04, 2026	Compound/ molecule
	US7851502	Feb 19, 2029	Formulation - Tablet
	US7919598	Jun 16, 2030	Polymorph
	US8501698	Dec 20, 2027	Polymorph & their composition
	US8221786/ US8361972/ US8716251	Sep 21, 2028	Formulation - Tablet
	US8329648/ US8906851	Feb 18, 2027	Treatment
	US8685934	Nov 26, 2030	Treatment
	US8721615	Jul 18, 2030	Device – irrelevant (Delist requested)

Patent Expiry and Generic Entry in United States Market:

The US Food and Drug Administration (FDA) approved over 15 generic versions of Farxiga (dapagliflozin) tablets on April 6, 2026, instantly following the expiration of the compound or molecule patent on April 4, 2026 with pediatric exclusivity (US6515117). Most of the generics enter in the market by following paragraph-III certification against molecule patent and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not

be infringed by generic companies against formulation patent which are expiring in 2029/ 2030.

Table 02: Dapagliflozin (Farxiga) tablet generic approval details [3]

S/N	Generic company name	ANDA Number	Approval date	Type of approval
1.	Inevntia	A211156	Apr 06, 2026	Final approval
2.	Sandoz	A211312	Apr 06, 2026	Final approval
3.	Micro Labs	A211467	Apr 06, 2026	Final approval
4.	Aurobindo Pharma	A211468	Apr 06, 2026	Final approval
5.	Biocon Pharma	A211470	Apr 06, 2026	Final approval
6.	MSN	A211478	Apr 06, 2026	Final approval
7.	Ajanta Pharma	A211482	Apr 06, 2026	Final approval
8.	Macleods Pharma	A211506	Apr 06, 2026	Final approval
9.	Aizant	A211523	Apr 06, 2026	Final approval
10.	Lupin	A211531	Apr 06, 2026	Final approval
11.	Cipla	A211535	Apr 06, 2026	Final approval
12.	Teva Pharma	A211541	Apr 06, 2026	Final approval
13.	Alkem Lab	A211545	Apr 06, 2026	Final approval
14.	Alembic	A211560	Apr 06, 2026	Final approval
15.	Zydus Pharma	A211582	Apr 06, 2026	Final approval
16.	Apotex	A211442	Jan 04, 2019	Tentative approval
17.	Hetero Labs	A211439	Jan 18, 2019	Tentative approval
18.	Sun Pharma	A211416	Aug 21, 2019	Tentative approval
19.	Glenmark Generics	A211564	Mar 20, 2030	Tentative approval
20.	Bionpharma	A211414	Dec 17, 2020	Tentative approval
21.	Jiangsu Hansoh Pharm	A216119	Apr 02, 2026	Tentative approval
22.	Sciegen Pharma	A219408	Apr 30, 2026	Tentative approval

CONCLUSION:

The primary molecule patent is the main barrier for generic launch. Once the molecule patent expires several generic players are ready with their product to launch on day one followed by patent expiry. Dapagliflozin continues to be a high-value molecule given its strong positioning in diabetes, heart failure, and chronic kidney disease segments. The upcoming phase could significantly reshape market competition and accessibility. Similar to the 2025 Indian market entry of generic competitors, the US market is expected to see significant price competition, with more than 60 active Drug Master Files (DMFs) for dapagliflozin in the US.

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