Generic Cabotegravir Timelines

DEC 2021: FDA Approval

JUL 2022: ViiV-MPP license signed

MAR 2023: MPP sublicense signed with 3 generic manufacturers

OCT 2023: Licensees accessed the complete tech pack from ViiV Healthcare by this time

Generic Manufacturers	2022	2023	2024	2025	2026	2027

NOW

API Development
Development of generic version of active pharmaceutical ingredient

Prototype Development
Development of generic version of approved product

(API)

Dossier Batch
Manufacture of a batch of generic product for regulatory submission

Pivotal Bioequivalence
Testing to demonstrate that generic API is absorbed in the body at the same rate as the approved drug

Dossier Submission
A package of bioequivalence data, sample product, and other information submitted to regulatory authorities and for WHO prequalification

Earliest submission to regulatory authorities and for WHO prequalification

- Timelines are not specific to any generic company; these are averages of timelines required for different activities as shared by MPP licensees.
- The earliest possible timelines for filing is Q3/4 2026 based on the current estimation by MPP.
- Due to the uncertainty associated with product development, especially for such long-acting products, the timelines quoted here are tentative and can change during development of the product.

Source: Medicines Patent Pool, May 2024.