



Bioequivalence

The FDA must establish that the generic drug has the same active ingredients, strength, dosage form and route of administration.

The drug should perform in the body in the same way as the brand-name drug.



Safety & Efficacy

The FDA must determine that the generic drug is as safe and effective as the brand-name drug. Generic drugs do not undergo extensive clinical trials, but they must demonstrate a similar safety profile.

Labeling & Packaging

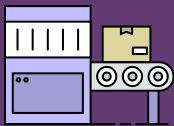
The manufacturer must ensure that the labeling and packaging for the generic drug is accurate, informative and consistent with that of the brand-name drug.

BIG QUESTIONS

How are Generic Drugs Approved?

The FDA has a rigorous approval process for generic drugs, ensuring they are safe and effective.

Generic drugs undergo thorough testing, and manufacturers must meet multiple requirements to obtain approval.



Quality & Manufacturing

Generic drug manufacturers must adhere to FDA best practices to ensure their drug's quality, consistency and purity. They must provide detailed information about the manufacturing processes, facilities and controls that ensure the quality of the generic drug.

Approval Decision



Once the FDA reviews all the information provided, regulators determine whether the generic drug is safe, effective and high-quality.

In the case of unresolved safety or efficacy concerns, the FDA may not grant approval for the generic drug. Regulatory authorities prioritize public health and patient safety.

