BIG QUESTIONS

How are Generic Drugs Manufactured?

Generic drugs must be manufactured under the same strict standards as brand-name medicines.

Drug Production

The FDA requires generic drug manufacturers to produce batches of the drugs and provide manufacturing information for the FDA to review. Manufacturers must provide evidence that each step of the process will produce the same result each time.

Facility Review

FDA inspectors visit the manufacturer's facility to:

Ensure they are capable of making the drug consistently

Confirm that the information the manufacturer has submitted to the FDA is accurate

Efficacy Standards

The FDA requires the drug to:

Function the same way within the body

Contain identical active ingredients

Adhere to the same guidelines as its brand-name counterparts

Container Quality

The container that the drug is shipped in must be approved by the FDA to ensure the drug's quality does not deteriorate.

Stability Testing

Generic drug companies do months-long tests to show that their medications have a reasonable shelf life.

GENERICS | ACCESS | PROJECT