

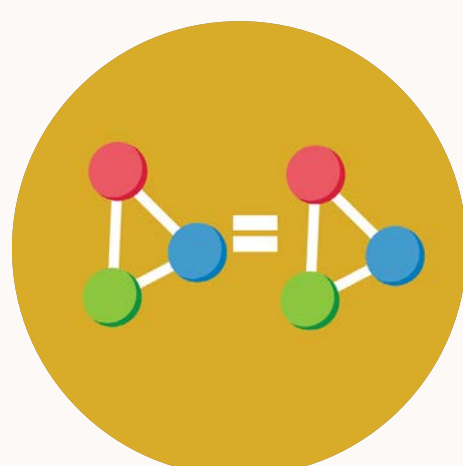


What Makes a Generic the Same as a Brand-Name Drug?

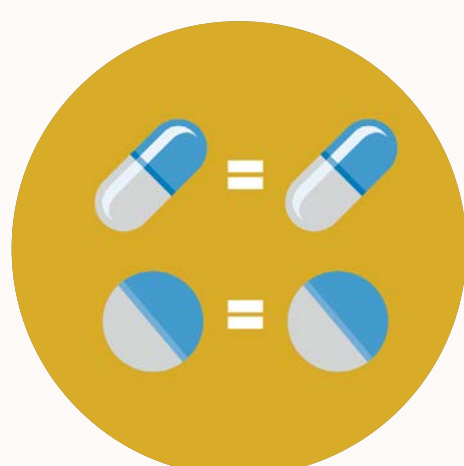


Pharmaceutical Equivalence

Lab test results and other documentation from the generic manufacturer are reviewed by FDA to demonstrate that:



The generic drug has the same active ingredient(s) as the brand-name drug.



The generic drug has the same dosage form as the brand-name drug.



The generic drug has the same strength and route of administration as the brand-name drug.



The generic drug has the same indications as the brand-name drug.



The inactive ingredients of the generic drug are safe and don't change how the drug works.



The generic drug will work as intended for a reasonable amount of time before expiring.

Bioequivalence

Comparisons—often in human volunteers who take both the generic and brand-name drugs—ensure that:



The generic drug performs the same in the human body as the brand-name drug.

Appropriate Container and Labeling

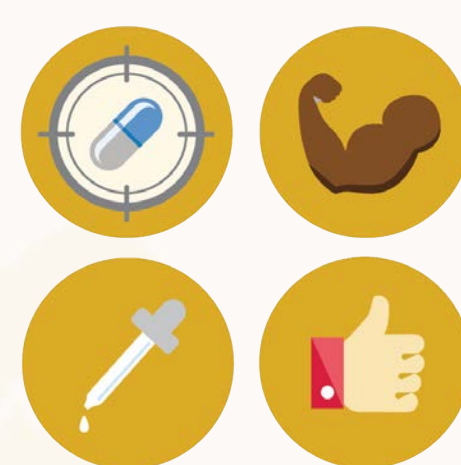
FDA inspection of the container and labeling demonstrates that:



The generic drug's label is the same as the brand-name drug's label, with some exceptions—such as indications protected by patents or exclusivity.

Appropriate Manufacturing

FDA inspection of facilities demonstrates that:



The generic drug meets the same requirements for identity, strength, purity, and quality as the brand-name drug does.

The generic drug is as safe and effective as the brand-name drug.



The generic drug is sold and shipped in an appropriate container.



The manufacturer is capable of making the generic drug correctly and consistently.



Visit www.FDA.gov/GenericDrugs to learn more.



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