

# Generic Medicines Are the Same as Their Brand Counterparts

## Bioequivalence Means FDA Standards Ensure Brand and Generic Medicines are Equally Safe and Effective

### Generics: Same Medicine, Same Results as Brands

By law, a generic medicine must meet the same high standards as its brand counterpart to receive approval from the Food and Drug Administration (FDA). FDA must ensure that the generic and brand have the same amount of active ingredient, strength, dosage, labeling and use. Generics must also comply with the same high quality manufacturing standards as the brands.

An active pharmaceutical ingredient is the component that makes the drug work in the body. To be approved by the FDA, the generic medicine must contain the same amount of active ingredient as the brand. Inactive ingredients are colorings, flavorings, and binders – and they may be different because of brand patents. However, these differences have no impact on safety and efficacy. In fact, all inactive ingredients used in generic drugs must be approved by the FDA. Generic and brand companies generally obtain their active and inactive ingredients from the very same suppliers.

### Bioequivalence: FDA Requires that Generics Prove They Have the Same Effect as Brands

To gain FDA approval, generic manufacturers must prove that their medicines are bioequivalent, to the brand, which means that the generic medicine must have the same effect in the body. As the FDA explains on its website, “since the safety and efficacy of the brand-name product has already been well established in clinical testing and frequently many years of patient use, it is scientifically unnecessary, and would be unethical, to require that such extensive testing be repeated in human subjects for each generic drug that a firm wishes to market. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to the pioneer [brand] drug.”

Bioequivalence studies are conducted with human volunteers in order to prove that the generic version of a drug delivers the same amount of active ingredients into a patient's bloodstream in the same amount of time as the brand drug. These studies assure equivalence. FDA also applies statistical measures to further assure the accuracy of the bioequivalence data.

### Don't Be Misled

Some brand manufacturers wage constant misinformation campaigns about bioequivalence. While bioequivalence may be scientifically complex, the result is simple: if the generic does not have the same result as the brand, it does not get approved.

Let's get the issue on the table: two formulations that differ in rate or extent of absorption by -20% to +25% or less are generally considered bioequivalent. This measurement is often misinterpreted, according to the FDA, to mean that a generic can differ by potency or blood level by as much as 20% less or as much as 25% more from the brand drug. This is incorrect, since statistical criteria are used to assure sameness. The observed variation is usually less than 3.3%, according to FDA studies. FDA firmly states that this minimal difference is clinically indistinguishable. The difference between a generic and a brand product is no more or less than the difference allowed between separate batches of the brand product.

### **Ensuring Safety and Efficacy of Generics Goes Beyond FDA Approval**

Once a generic medicine is on the market, generic manufacturers are required to assure the safety of their products through post-marketing surveillance and reporting. Consumers should be assured that generic medicines contain the same medicine as the brands. That's the responsibility of our industry and the responsibility of the FDA. Ours is a complex, highly regulated industry with dedicated scientists who work hard every day to develop and manufacture safe and effective, high-quality medicines that meet FDA's rigorous standards. The public deserves nothing less.

**Generics...**  
**The right choice for better health.™**

**GPhA**

GENERIC PHARMACEUTICAL ASSOCIATION®