

Quality Generics ^[1]

With roots dating back more than 120 years and as a division of Novartis, Sandoz is a trusted leader with a reputation for exceptional quality. Our core business lies in developing, producing, and distributing high-quality medicines following the loss of their respective patent protection, thus helping secure access to affordable, quality healthcare for patients in the US.

While generics may differ with respect to their shape, size, or color, they contain the same active ingredients as the original product and are therapeutically equivalent to and substitutable for the brand product.

Since generic medicines contain the same active ingredients as the brand product, full clinical trials are not required in generic development; rather, we establish the drug's bioequivalence and demonstrate to the FDA that equivalent dosing has the same effects within the human body as the reference product.

Generic medicines also offer the same quality and safety profiles as reference products. Throughout their development and production processes, generics are required to adhere to the same rigorous standards of quality, safety, and efficacy as originator products, standards that are closely monitored and enforced by the US Food and Drug Administration (FDA) both prior to and post product approval. Production facilities are thus regularly inspected to ensure that they are cGMP (current Good Manufacturing Practice) compliant, while marketed products are regularly monitored to ensure the highest quality standards.

Accordion Type:

- Collapsible

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