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Quality of generic Viagra® (sildenafil citrate) on the internet: What are the health risks?

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Background: The accessibility of prescription drugs produced outside of the U.S., most notably sildenafil citrate (innovator product, Viagra®) has been made much easier by the internet. Of greatest concern to clinicians and policymakers is product quality and patient safety. The U.S. Food and Drug Administration (FDA) have issued warnings to potential buyers that the safety of drugs purchased from the internet cannot be guaranteed, and may present a health risk to consumers from substandard products.

Objective: To determine whether generic sildenafil citrate tablets from international markets obtained via the internet are equivalent to the U.S. innovator product regarding major aspects of pharmaceutical quality: potency, accuracy of labeling, and presence and level of impurities. This will help identify aspects of drug quality that may impact public health risks.

Methods: Fifteen sildenafil citrate tablets were obtained from for pharmaceutical analysis: fourteen generic samples from international internet pharmacy web sites and the US innovator product. According to U.S. pharmacopoeial guidelines, tablet samples were tested using high performance liquid chromatography (HPLC) for potency of active pharmaceutical ingredient (API) and levels of impurities (Impurity A, B, C, D). Impurity levels were compared to International conference on harmonization (ICH) limits.

Results: Among the 15 samples, 2 samples possessed higher impurity B than ICH qualification limit, 5 samples possessed higher impurity C than ICH qualification limit, 4 samples possessed more than 1% impurity quantity of MDD (maximum daily dose). In addition, an unknown compound was identified, which is suspected to be a previously unidentified impurity. For API, 5 of the samples failed to fall within the 5% assay limit.

Conclusions: Quality assurance tests are often used to detect formulation defects of drug products during the manufacturing and/or storage process. Results suggest that manufacturing standards for sildenafil citrate generic drug products compared to the U.S. innovator product are not equivalent with regard to potency and levels of impurities. These findings have implications for safety and effectiveness that should be addressed by clinicians to safeguard consumers who choose to purchase sildenafil citrate and foreign-manufactured drugs, in general, via the Internet.

Key Words: Sildenafil citrate, Viagra®, drug importation, internet pharmacy, drug quality, drug safety, quality assurance testing

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