

Investigation of the interchangeability between Cefuroxime Axetil tablets marketed in Palestine. Is there a quality reason behind the price?

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Abstract

Background:

According to Food and Drug Administration (FDA), therapeutically equivalent antibiotics are expected to have equivalent clinical efficacy and safety when used under the conditions of their labeling. However, any defect in the quality of an antibiotic may negatively affect its efficacy and safety and accordingly are considered a substandard drug. Cefuroxime is a semi-synthetic, broad-spectrum cephalosporin antibiotic intended for oral administration. Any quality defect in this product may cause inefficacy and future bacterial resistance.

Objective:

The aim of this study was to evaluate the quality and cost price of all commercial Cefuroxime Axetil tablet products available on the Palestinian market (One brand and two generic products).

Method:

A survey on the price of all commercial tablet products was conducted. To assess quality, all products were examined visually for their general appearance. They were tested for weight uniformity, friability, disintegration, and dissolution profile, and assayed for Cefuroxime content.

Results:

The original brand was more expensive than the two locally produced generic products. Based on our testing procedure, all Cefuroxime tablet products were equivalent to the brand product. Although, the two generic products released more than 85% of their Cefuroxim content within 15 minutes, while the brand released only 74.5%.

Conclusion:

These results demonstrate that generic Cefuroxime tablets produced by local manufacturers are often comparable in vitro to the brand product and have lower price. Accordingly, we encourage our physician to prescribe the local product since they may be interchangeable and have same safety and efficacy profile.