

**Title :** Comparison of Preservative Content in Medicinal Product in Different Packaging : Amber Plastic Bottles and Sachets.

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## ABSTRACT

Liquid formulations of drug A require preservatives such as methylparaben and propylparaben to prevent microbial contamination during storage. However, external factors such as packaging, light, humidity, and oxygen may influence the stability and concentration of these preservatives. This study aims to compare the preservative content in drug A stored in amber plastic bottles and sachets using ultra-performance liquid chromatography (UPLC). The results showed that after 12 months of storage, the levels of methylparaben and propylparaben in both packaging types decreased compared to the labeled values. Statistical analysis was performed using the paired t-test. The average % label amount (LA) of methylparaben in amber plastic bottles and sachets was  $55.04 \pm 0.78\%$  and  $54.82 \pm 0.02\%$ , respectively, which were not significantly different ( $p > 0.05$ ). However, the %LA of propylparaben was  $73.06 \pm 1.24\%$  and  $70.18 \pm 1.26\%$ , respectively, which were significantly different ( $p < 0.05$ ). Additionally, the %w/v of methylparaben in both packaging types was 0.22%, whereas the %w/v of propylparaben in amber plastic bottles and sachets was 0.04%. These values were lower than the labeled concentrations, which specify that methylparaben and propylparaben should be present at 0.4% w/v and 0.06% w/v, respectively. The lower residual amount of propylparaben in sachets compared to amber plastic bottles suggests that the preservative may have adsorbed onto the sachet walls, leading to uneven distribution and potential loss. These findings provide valuable insights into selecting appropriate packaging to minimize preservative loss and enhance product stability. However, further studies on the distribution of preservatives in different packaging materials, as well as the influence of environmental factors, are necessary to optimize the storage and preservation of drug A formulations.

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