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Evaluation of quality and stability of spironolactone tablets stored in different household conditions

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The quality and stability of a pharmaceutical product is important for its therapeutic effectiveness. Packaging material and storage conditions may affect the stability of a medication. Spironolactone is a diuretic medication used to treat cardiovascular diseases. This study aimed to assess the quality and stability of spironolactone tablets stored in simulated household conditions. Seven samples of Spironolactone 25 mg tablets (n=107 each) with the same lot number were obtained. One sample was subjected to visual inspection of appearance, weight variation, chemical assay, dissolution, disintegration, friability, and hardness tests according to British Pharmacopoeia at the baseline. Other six samples were stored for 30 days; two samples in the original packaging (OPS), and four as repacked samples (RPS). OPS were stored under standard storage conditions (below 30ºC, protect from moisture, heat, and sunlight) and on a table. The RPS were stored at standard conditions, on a table without a container, in a closed cupboard, and within a used metal container. After 30 days, the same tests were performed. The RPS kept on a table failed assay (78.16 ± 0.56) and dissolution tests (79.39 ± 24.83) and showed discoloration of tablets. All RPS in household conditions failed the hardness (36.09 ± 1.73, 25.75 ± 5.24, 32.61 ± 4.44) test and had significantly different results with the OPS sample for weight variation test (p values: 0.022, 0.012, 0.006). The stability of repackaged spironolactone 25 mg tablets stored in typical household conditions cannot be guaranteed after 30 days. However, the stability can be maintained for 30 days in their original packaging. Hence, it is important to advise the patient on suitable household storage conditions.

Keywords: Chemical assay, diuretic medication, repacked samples, stability

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