Comparative Study of Physicochemical Properties of Paracetamol Injection Marketed in South East, Nigeria.

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Background: Substandard medicines are widespread and represent a threat to health because they can lead to healthcare failures, such as antibiotic resistance and prolonged stay in hospital as well as death. The estimated overall prevalence of poor-quality medicines was found to be 13.6 %. Because of this, physicians encounter problems in the selection of quality brands of drugs.

Aim: To determine the quality of Paracetamol injection brands, a comparative study on the physicochemical properties of the injection was done.

Method: Eight brands of Paracetamol injections were analyzed. Physicochemical properties were evaluated including physical examination and pH determination. Drug content was assayed using ultra violet spectroscopic method according to British Pharmacopoeia (BP). Quantitative determination of bacterial endotoxin test was also carried using Limulus amoebocyte lysate (LAL) test.

Results: Physical examination of the original and all generics showed no presence of particles and colourless. The pH of all the brands ranged from pH 4.67 – 5.89 and four brands were outside official specifications. Drug assay showed paracetamol content of only three brands complied with British pharmacopeia standard of 95 – 105%. The bacterial endotoxin concentration of all the injections complies with the standard specification since all contain less than 0.5 EU/ml release limit.

Conclusion: Based on these results, 37.5% of Paracetamol injections complied with quality specifications.

Keywords: Substandard drugs, Paracetamol, Drug quality, Ultra Violet Spectroscopy, Limulus amoebocyte lysate test.