Physicochemical and Microbiological Assessment of Clarithromycin Tablets Marketed in Enugu State Nigeria

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Background: There is a widespread distribution of substandard and counterfeit drugs in developing countries. The potency of antibiotics is estimated by comparing the inhibition of the growth of sensitive microorganisms produced by known concentrations of antibiotics being examined with a reference substance. Clarithromycin is a macrolide antibiotic used for the treatment of a wide variety of bacterial infections such as acute otitis, pharyngitis, tonsillitis, uncomplicated skin infections, and helicobacter pylori infection.

Objectives: The study focused on the evaluation of the physicochemical and microbiology properties of the Clarithromycin tablet marketed in Enugu state by comparing the *in vitro* susceptibility of isolates of *Staphylococcus aureus* to various brands.

Methods: Clarithromycin tablets labeled A-D were sourced from various Pharmacies. All brands were evaluated for various physicochemical properties namely: physical examination, Chemical test, weight uniformity, and disintegration time. A microbiology assay was also conducted using the agar cup-diffusion method. *Staphylococcus aureus* clinical isolates were used for seeding the solidified nutrient agar plates. The diluted drug was introduced into the bored cup. Then the plates were kept in the incubator at 37^{o}C for 13 hours. Parameters monitored were inhibition zone diameter (IZD) and percentage drug potency which was determined from each brand IZD.

Results: Physical properties of all the brands were satisfactory in terms of colour and absence of mottling. Labeling guidelines were followed and no mistakes were detected in spellings for all the brands. The packaging materials of all the brands were clean. Weight uniformity tests of all the brands showed percentage deviation of less than ± 10%. Disintegration of all the brands was within 6mins. Microbiology results showed that all the brands had good potency with exception of Brand B. The percentage potency of all the brands lies from 100 to 112%. One brand failed the percentage potency test for being out of range of 95 – 105%.

Conclusion: Three brands passed physicochemical and microbiology parameters when compared to innovator product. Hence, they will elicit therapeutic responses on time thereby improving patient related quality of life.

Keywords: Clarithromycin, Substandard, physicochemical, microbiology assay, potency