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Quantitative assay of metal impurities and pharmaceutical quality evaluation of multisource Levofloxacin tablets registered in Nigeria

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Levofloxacin is a broad-spectrum antibiotic of the class fluoroquinolone. There are many generics of levofloxacin tablets available within the drug delivery system globally. This has placed health practitioners in dilemma of generic substitution. The serious toxic effect of arsenic and mercury has made the quantification in dosage forms necessary today. The post market surveillance studied on 15 brands of levofloxacin 500 mg tablets registered in Nigeria was aimed at assessment of the physicochemical quality of the brands and determination of the quantity of selected metal impurities. To determine the brands that could be substituted for the innovator brand using similarity factor. The concentration of selected metal (Hg and As) impurities in all the brands of levofloxacin 500 mg (LEV01 to LEV15) tablets were carried out using ICP-OES. The physicochemical parameters of evaluated using both official (USP) and unofficial standards including uniformity of weight test, hardness test, friability test, disintegration test, dissolution profiles and quantitative assay was carried out using high performance liquid chromatography. The concentration of mercury and arsenic in all the brands analyzed is below the Permissible Daily Exposure (PDE). The results showed that all the brands passed the physical tests except Lev 11, Lev 10 and Lev 01, 02, 09, 11 that failed the uniformity of weight test, disintegration test and hardness test respectively. Lev 09 failed the quantitative assay test. Only Lev 3, 6, 7, 8, 11, 13 and 15 can be substituted for the innovator brand Lev 01. All the brands manufactured in Nigeria (Lev 6, 11, 13) passed the similarity factor, f_2, test and therefore could be substituted for the innovator brand. The study showed that the locally manufactured levofloxacin tablets could be substituted for the innovator brand. The post market surveillance study of medicinal agents is a source of very important information for health practitioners.

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