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Quality assessment and in vitro dissolution profile: Comparison of different brands of amoxicillin

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Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. Counterfeiting occurs both with branded and generic products. The 2008 report of WHO on the estimation of the proportion of counterfeiting by category revealed that the most counterfeited drugs were in the genito-urinary category (37 percent) followed by anti-infective (12 percent) and central nervous system drugs (12 percent). Amoxicillin is one of the most susceptible medicines for counterfeiting in Ethiopia because of its high demand in the market. Ten brands of amoxicillin in solid oral dosage forms were subjected to analysis according to USP (2011) monograph for identification, uniformity of dosage units, assay and dissolution performance. Results indicated that all of the samples were in accordance with the pharmacopoeia specifications. However, seventy percent of the tested products fulfilled dissolution test after stage II. And hence, more study was done on the dissolution profiles of the capsules. The *in vitro* dissolution profiles were compared using dissolution efficiency model. Only one of the eight brands was found to be similar with the innovator brand. Therefore, from the study, it can be understood that even though ninety percent of the tested samples were not identical with the innovator brand, they fulfill the pharmacopeial requirements. Further studies need to be done on other anti-infective, genito-urinary and central nervous system drugs. Remarkable attention should be given for expensive, highly demanded and easily degradable medicines in order to assess and look into the existence of counterfeit and sub-standard drugs.

Biography

Lantider Kassaye Bekele is a Pharmacist by profession and has completed his MSc degree in Pharmaceutical Analysis and Quality Assurance from Addis Ababa University, Ethiopia. He had worked in Food, Medicine and Healthcare Administration and Control Authority (FMHACA) of Ethiopia in different positions. He has published more than five scientific papers in the international journals in his field. He was the Chairperson of the National Technical Committee for Standards of Alcoholic Beverage. He has served as a Member of Pharma Forum Committee, Ethiopian Pharmaceutical Association. Moreover, he was a Member of Drug Advisory Committee of the Regulatory Authority. Currently, he is working for GlaxoSmithKline Ltd as Regulatory Executive for Ethiopia and Djibouti.

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