ASSAY OF RETAILED ESOMEPRAZOLE 40 MG TABLETS USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY: A CASE STUDY OF NANYUKI TOWN.

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ABSTRACT

Esomeprazole magnesium (hereafter referred to as esomeprazole) is a proton-pump inhibitor (PPI), which works through an inhibition of the final step in the production of gastric acid by selective inhibition of the H+/K+ ATPase located in the secretory membranes of the parietal cells in the gastric oxyntic mucosa. Esomeprazole is the pure S-enantiomer of the racemic omeprazole. Percentage content of esomeprazole magnesium in retailed 40 mg tablets in Nanyuki town, Kenya, was determined using a High Performance Liquid Chromatography method. Six brands of esomeprazole 40 mg tablets were used in the study. Assay for the content of active ingredients was performed using the HPLC method described in the United States Pharmacopoeia (USP 2013). The study was conducted at Mount Kenya University laboratory of pharmaceutical chemistry between May and August, 2013. The analysis was carried out using a cyberlab LC 100 HPLC machine, with a LC 100 pump and a LC 100 UV detector. The test samples were prepared in such a way that the solutions to be injected contained the active ingredients in the concentration of 0.04 mg/ml. Injection was carried out manually using a Rheodyne injector with a 20µ loop volume and separation done using an ODS Hypersil C18 (15 cm × 4.6 mm; 5 µm) column. The flow rate was set at 1.0 ml/min and detection carried out at 302 nm. The mobile phase used was a mixture of acetonitrile, buffer and distilled water at a ratio of 35: 50: 15 (v/v) respectively. The column temperature was maintained ambient by use of a water bath. The mean retention time of the samples is 3.03. Do the retailed esomeprazole 40 mg tablets in Nanyuki town conform to the USP (2013) acceptance criteria? The esomeprazole tablets included in the study had a drug content of between 95.47% - 104. 40% which is within the compendia tolerance limits. It is therefore important to note that all the esomeprazole 40 mg tablets analyzed complied with the pharmacopoeial specifications as described in the USP (2013).This indicates that the products analysed meets the standards set for their distribution in Kenya.