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To carry out the quality control tests and release studies on different available brands of levofloxacin

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Abstract:

Levofloxacin is a broad-spectrum, third-generation fluoroquinolone antibiotic and optically active L-isomer of ofloxacin. It is an antibiotic that is active against both Gram-positive and Gram-negative bacteria and is used to treat a number of bacterial infections including acute bacterial sinusitis, pneumonia, H-pylori (in combination with other medication), urinary tract infections, chronic prostatitis, and some types of gastroenteritis. Quality control is the set of measures and procedures to follow in order to ensure that the quality of a product is maintained and improved against a set of benchmarks and that any errors encountered are either eliminated or reduced.

Invitro profile also helps us to get an idea of how drug will behave in-vivo. Different brands of Levofloxacin tablets are known to show different Pharmacokinetic parameters and release profiles. A study was planned because of lack of data about Quality Control tests on Levofloxacin tablets available in Oman. The objectives of our study were to carry out dissolution rate studies on all the available brands and to find out the best brand in terms of the Quality Control test parameters and release of the drug from the formulations.

Four brands of Levofloxacin 500 mg tablets marketed in Oman were pharmaceutically evaluated via weight variation, hardness, friability, thickness, disintegration, and dissolution studies to assess their Pharmaceutical equivalence. Pharmacopeia demands that all the tablets must meet quality control standards. A linear graph was obtained with a regression coefficient of 0.9988 using the pure drug. UV Spectrophotometric method was used for the determination of Levofloxacin in dosage formulations and λmax chosen for analysis was 290nm. All the brands passed the tests although the variation was observed on comparison.

In release studies, one brand showed the highest Tmax of 150 minutes with a Cmax value of 13.25 µg/ml, which is the lowest Cmax value compared to the rest of the brands. One brand however reached its maximum concentration within 30 minutes. Although the four brands showed variation in their release properties, they met the U.S.P. Quality Control requirements. The detailed results will be presented.

Objective: The objective of the current study was to evaluate the quality control parameters of seven brands of levofloxacin 500 mg film-coated tablet available in the Yemeni market.

One of the most prescribed drugs in modern medicine is antibiotics. They are widely used to treat bacterial infections by killing or inhibiting bacteria. Levofloxacin is a synthetic fluoroquinolone agent; it has a broad spectrum to fight different kinds of bacteria in the body of Gram-positive and Gram-negative organisms for oral and intravenous administration. Chemically, it is the pure (-)-(S) enantiomer of the racemic drug substance Ofloxacin. Levofloxacin is widely used in the treatment of bacterial infections of the skin and urinary tract infections, as well as upper and lower respiratory tract infections, such as acute bacterial sinusitis, acute exacerbations of chronic bronchitis, and community-acquired pneumonia. A film coated tablet has some advantages over other types, as it is covered with a coating to mask the unpleasant odor and taste, to allow the tablet to pass into the small intestine without disintegration in the stomach, and to enhance the stability and strength of the tablet. Biochemical and pharmacological quality control tests for different brands of pharmaceutical products that contain the same active ingredients are vital steps to confirm therapeutic equivalence for such products.

Additionally, oral dosage forms depend profoundly on dissolution studies in vitro to predict their bioavailability in vivo. Furthermore, the official and unofficial quality control tests in vivo-in vitro are required to confirm the safety and efficacy of any pharmaceutical product. In Yemen as well as other poor countries, the price of drugs is the main factor in determining patient's access to health care, where many people put off the use of needed medicines due to the high cost of branded products. Moreover, few studies have been conducted so far to evaluate drugs' quality control in Yemen. Therefore, further studies should be conducted in this field to evaluate the quality control tests for locally and internationally manufactured drugs, to ensure the quality and efficacy of the pharmaceutical products, and to offer suitable substitutions to patients. Even though there are many different brands of levofloxacin available in the Yemeni market and the clinical use of levofloxacin is highly increased among the public, there is no quality control study has been conducted on this field in Yemen. The findings of this study can be used as a source of information to drug regulatory authorities and drug manufacturers in Yemen. Accordingly, this study was aimed to evaluate the quality control of different brands of levofloxacin 500 mg film-coated tablet available in the Yemeni market.

Methods: Physicochemical parameters assay was performed for seven brands of levofloxacin 500 mg film-coated tablet. Each brand was subjected to official and unofficial in vitro quality

control tests, including weight variation, thickness, hardness, friability, disintegration, dissolution, and content uniformity assay by High-Performance Liquid Chromatography (HPLC).

Results: Out of seven, six brands of levofloxacin 500 mg film-coated tablet passed official specified assay tests according to the United States Pharmacopeia (USP) specifications. They showed a similar profile of thickness ranged between±0.01 and 0.10%, friability ranged between 0.01% and 0.34%, disintegration time ranged between 3.00 and 15.00 min, dissolution percentage ranged between 90.650 and 103.05 and content uniformity ranged between 93.62 and 107.12%. Regarding weight variation and hardness, six brands passed the weight variation test and only three brands showed optimum range (10-20 kg) of hardness test. A. Only one brand failed to pass the weight variation test, and four brands failed to pass the optimum range (10-20 kg) of hardness.

Conclusion: There are no remarkable differences between the seven brands regarding in vitro quality control tests of content uniformity, thickness, friability, disintegration, and dissolution. Even though four brands were above the optimum range of hardiness, they showed complete disintegration and dissolution within the acceptable limit. Regular assessment of marketed drugs is required to ensure bioequivalent to their innovators.