



Physical Characterization and *In Vitro* Evaluation of Some Generic Medications Available in Pharma Market of United Arab Emirates (UAE)

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SUMMARY. This study is the first attempt in UAE to prove the trustworthiness of the *in vitro* evaluation to assess the reliability of the generic medications comparing to the brand name. Five generic medicines, two Local (codes: L1, L2), three Arabic (codes: A1, A2 and A3) and the International brand (code: I1) of diclofenac sodium (DS) sustained release tablets, as a model product, was collected randomly from the UAE pharma market. The products were characterized by physical parameters including weight variation, thickness, friability, hardness and moisture content. The *in vitro* release study was conducted in simulated gastric medium (0.1 N HCl, pH 1.2) for 2 h and simulated intestinal medium (phosphate buffer pH 6.8) for 9 h using type II (paddle type) USP reference dissolution apparatus. The drug was assayed by using UV spectrophotometry at 277 nm. Different kinetics models were applied to drug release data in order to evaluate mechanism of drug release. Physical properties of all products compiled with the acceptable limits. However moisture content was higher than the standard value in the generic products except the brand. All the products succeed to fulfill their official requirement of 80 % drug release within 8 h, in simulated intestinal medium except A3. Zero order release kinetics was predominant for all L2 and the International brand while more data fitting to Hixson- Crowell kinetics was obtained with the L1 and A1, A2 and A3. The results of our study question the suitability of the generic products as a replacement for the branded product. Therefore, we strongly suggest that evaluation on the marketed samples has to be made in order to establish bioequivalency between the branded and the generic products.

KEY WORDS: *In vitro* evaluation, Generic medication, UAE, Kinetic analysis, Diclofenac sodium.

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