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Pharmaceutical Quality Control Studies on Gatifloxacin 200 mg Tablets Available in the Pakistani Market

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SUMMARY. The aim of present work was to compare the quality of different brands of gatifloxacin 200 mg tablets, collected from different retail pharmacies in the local market of Pakistan. Five different brands were characterized by physical and chemical parameters such as, weight variation, hardness, thickness, friability, disintegration, dissolution, uniformity of contents and assay. Among them dissolution either single point or multiple point, including release profile comparison is most important tool for establishing the quality of the product. Brand A was considered as a reference because it passed all physical, chemical, quality control test and it was also brand leader, while brands B, C, D and E were test brands due to their production in local pharmaceutical. Quality control tests were satisfactory and within the limits for all test brands. The aim either biowaiver study of all the brands should conduct or not the similarity and difference among the brands were measured. Results revealed that brand B and D shown the best similarity with brand A and least differential value when we used the model independent f₂ factor for similarity and f₁ factor for difference. Model dependent methods Zero order, First order, Higuchi release model and Hixson-Crowell method were also used and shown the concentration dependent release of drug, i.e. first order kinetic. The results showed that model-dependent methods were more discriminative than model-independent method. A criterion for selecting the most appropriate model was based on linearity (coefficient of correlation).

KEY WORDS: Biowaiver, BCS class I, Gatifloxacin, Model-independent and model-dependent methods.

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