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Comparative analysis of ofloxacin tablets: Assessing bioequivalence and post-compression parameters in brand, generic, and in-house formulations

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Abstract:

Ofloxacin is a second generation Fluoroquinolone, whose primary mechanism of action is the inhibition of bacterial DNA gyrase. It is used widely for the therapy of mild-to-moderate bacterial infections. Various brand and generic versions of Ofloxacin tablets are available in the market with the general claim that they all are bioequivalent. In the present study, an attempt is made to compare and evaluate post compression parameters of brand, generic and prepared Ofloxacin tablets containing 200 mg of the drug and to determine whether all formulations used were equivalent or significantly different. Ofloxacin tablets were prepared by wet granulation method by using different ingredients like carboxy methyl cellulose and dicalcium phosphate. All the formulations including brand, generic and prepared Ofloxacin tablets were analyzed for their weight variation, hardness, friability, drug content, in vitro disintegration and in vitro dissolution profile and results were found to be present within the prescribed limit. The drug release from branded drug products was slightly higher compared to generic drug products procured from the market and prepared in-house. All the findings and outcomes have shown that brand, generic and prepared formulations exhibit better response.

Keywords:

ofloxacin tablets, Fluoroquinolone, Generic drugs, FDA standards, critical manufacturing variables