# Biowaiver Monographs for Fexofenadine Immediate Release Tablets

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## Abstract

**Background:** Safety, efficacy and high-quality product must be proven when an abbreviated new drug product (ANDP) is submitted to the ministry of health for approval. This may imply bioequivalence studies (BEs) which are costly and time-consuming. Currently, biowaiver studies have been applied based on BCS (class I, week acid class II, and III ) to attain the drug product approval without the need to perform BEs. **Purpose:** This study is sought to investigate if Fexofenadine (FD) immediate-release tablets (180 mg/tablet) could be qualified for biowaiver instead of BEs. **Method:** Analytical HPLC method was verified to test the amount of FD in the tablets and in the dissolution studies. The generic FD tablets were assessed for critical quality attributes (CQA) an other biowaiver criteria. Dissolution profiles for both (generic and brand) were conducted at pH values (1.2, 4.5 and 6.8).

**Results:** The analytical method proved its suitability for the analysis of FD based on the results of system suitability, linearity, precision, recovery, and accuracy which were within the accepted ranges as per the guidelines. FD tablets showed CQA comparable with those of the original brand. They showed the release profile greater than 85% within 15 min in the different pH media. **Conclusion:** According to ICH and other regulatory authorities, FD IR oral solid dosage form fulfilled all the requirements for the drug to be biowaved and justify the candidature of interchangeability between RLD and brand version of the highest dose strength (180mg/tablet).

**Keywords:** Fexofenadine, Biowaiver, Bioequivalence, Release, BCS