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Dissolution Profile Comparison of Generic Atorvastatin Tablets for Biowaiver Justification

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Abstract: *This study aims to evaluate the biowaiver eligibility of five generic Atorvastatin 20 mg tablet formulations by comparing their in vitro dissolution profiles with a branded reference product. Dissolution testing was conducted in three media (pH 1.2, 4.5, and 6.8) using USP Apparatus II (paddle method) at 50 rpm and 37 ±0.5°C. The similarity factor (f_2) was calculated to assess dissolution profile equivalence. Additional parameters such as Mean Dissolution Time (MDT) and Dissolution Efficiency (DE) were evaluated to support the analysis. Three generic formulations demonstrated f_2 values greater than 50 across all tested pH conditions, indicating similar dissolution behavior to the branded product. Two formulations failed to meet the similarity threshold at pH 6.8, suggesting potential bioavailability concerns. Variability in dissolution was attributed to formulation differences, particularly excipient choice and manufacturing technique. The results suggest that select generic Atorvastatin formulations exhibit dissolution profiles comparable to the branded reference, supporting their consideration for biowaiver approval under regulatory frameworks that accept robust in vitro data. However, product-specific factors and inter-formulation variability emphasize the need for cautious, case-by-case assessment.*

Keywords: Atorvastatin, Biowaiver, Dissolution, Generic drugs, BCS Class II, Similarity factor (f_2), Bioequivalence, Regulatory science

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