Development and Validation of a Reverse Phase-High Performance Liquid Chromatography Method for The Assay of Benazepril Hydrochloride Using A Quality By-Design Approach	
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SUMMARY. According to ICH guidelines, the development and validation of reverse phase-high performance liquid chromatography (RP-HPLC) procedures for atenolol were validated using quality by design (QbD) methodologies. For atenolol flow rate, water concentration, and column temperature were identified as critical method parameters (CMPs) from risk assessment and factor screening studies, and evaluated for their influence on retention time (RT), and tailing factor (TF) for the drug atenolol as critical analytical attributes (CAAs) using a central composite design. Atenolol was separated using a Waters Atlantis T3 column (250 × 4.6 mm ×5 m) with mobile phase in the ratio 59 mM potassium phosphate buffer (pH 5.4):methanol (69:31), at a flow rate of 0.59 mL/min, with UV detection at 225 nm and acetonitrile:..water (60:40) at a flow rate of 1.1 mL/min. Atenolol's retention time was determined to be 6.31 min. Specificity, linearity, accuracy, and precision were all verified, and the results were good. At concentrations ranging from 10ng/mL to 60 ng/ mL, the approach proved cost-effective, accurate, precise, and linear.