Development and Validation of a Reversed-Phase HPLC Method for Simultaneous Determination of Doxazosin Mesylate and Finasteride in Pharmaceutical Dosage Forms

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**Purpose**
Medical treatment for men with lower urinary tract symptoms and prostatic enlargement secondary to benign prostatic hyperplasia (BPH) is 5 alpha-reductase inhibitor monotherapy or co-administration with alpha-blocker. Combination products offer an attractive solution to some complex therapeutic problems. However, formulation of combination products could be challenging due to drug-drug interaction, stability, and assigning an appropriate expiry date of the combined products. The purpose of this project is to develop and validate a RP-HPLC method for simultaneous determination of doxazosin mesylate (alpha-1 selective blocker) and finasteride (5 alpha-reductase inhibitor) in a single unit dosage form. The method will be used to study the stability and compatibility of the two drugs in a single dosage form.

**Methods**
A stability-indicating RP-HPLC method was developed and validated for simultaneous determination of doxazosin mesylate (DOX) and finasteride (FIN). The method was validated for linearity, accuracy, precision, detection limit (DL) and quantitation limit (QL).

**Results**
A simple reversed-phase high-performance liquid chromatographic (RP-HPLC) method was developed and validated for simultaneous determination of doxazosin mesylate (DOX) and finasteride (FIN). The compounds were separated on an analytical column (C18; 250 x 4.6mm, 5µm) with a mixture of ammonium acetate (10 mM, pH 4.0)/acetonitrile (50:50) as mobile phase at a flow rate of 1.0 mL/min. UV detection was performed at 246 nm. Total chromatographic analysis time per sample was 15 min with DOX and FIN retention times of 3.09 and 6.12 min, respectively. Validation studies revealed the method is specific, rapid, reliable, and reproducible. Calibration plots were linear over the concentration ranges 1.1 –117 µg/mL and 9 – 911 µg/mL for DOX and FIN, respectively.

**Conclusion**
A simple isocratic RP-HPLC method with UV detection has been developed for simultaneous determination of DOX and FIN. The high recovery and low relative standard deviation confirm the suitability of the method for determination of DOX and FIN in pharmaceutical formulations.