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# Simultaneous Determination of Tamulosin Hydrochloride and Finasteride in Formulations by Reverse-Phase HPLC

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A simple, precise, rapid, reproducible and selective reverse phase HPLC method has been developed for the estimation of tamsulosin hydrochloride and finasteride in capsules. This method is based on using hypersil C 18, 5 μ column having 250 × 4.5 mm i.d., in isocratic mode with mobile phase of acetonitrile and water in the ratio of 60:40 v/v. The flow rate was 1 mL/min and efluents were monitored at 240 nm. The retention times of tamsulosin hydrochloride and finasteride were 3.92 and 5.45 min respectively and linearity ranges were in the range of 0.2-0.8 μg/mL and 2-10 μg/mL respectively.

**Key Words: Estimation, Finasteride, Tamsulosine hydrochloride, HPLC.**

## INTRODUCTION

Finasteride (FNS) is chemically (5,17β)-N-(1,1-dimethyl)-3-oxo-4-azaandrost l-ene-17-carboxamide. It is 5-alpha reductase inhibitor, which converts testosterone to dihydrotestosterone (DHT). Conversion of testosterone to dihydrotestosterone is essential for prostatic hyperplasia[1]. Tamsulosin hydrochloride (TMS) is chemically 5(2-((-(2-ethoxy phenoxy) ethyl) amino) propyl)-2-methoxy benzene sulfonamide[2]. It is selective alpha adrenoreceptor blocking agent. These alpha 1 adrenoreceptors are most abundant in the prostatic capsule and bladder neck. Blockade of these adrenoreceptors can cause reduction of prostatic hyperplasia symptoms. An *in vitro* study revealed that the selectivity of this drug to prostate alpha 1 receptors was about 10 times higher than to aorta alpha 1 adrenoreceptors[3,4]. HPLC[5-9], LCMS[10,11], spectrophotometric[12,13], polarographic[14] methods have been reported in the literature for the estimation these two drugs in individual dosage forms and in biological fluids. These two drugs are used together in benign prostatic hyperplasia. No method has been found for the simultaneous estimation of these two drugs. Therefore authors attempted to develop a simpler and cheaper analytical method for simultaneous estimation of finasteride and tamsulosin hydrochloride in

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bulk and capsule dosage form.

## EXPERIMENTAL

An isocratic HPLC systems (Shimadzu) consisting of LC-10 at liquid pump, SPD-10A VP UV-Visible detector, an ODS C-18 RP column (4.6 mm I.D × 250) 25 μL Hamilton injecting syringe and Spinchrome software was used. Shimadzu AS200 electronic balance was used for weighing the materials. Pure samples of tamsulosin hydrochloride and finasteride were used. Acetonitrile, used was of HPLC grade obtained from Merck (India) Ltd., Mumbai. Water used was triple distilled prepared by all-glass distillation apparatus.

**Standard graph:** Standard stock solution of tamsulosin hydrochloride and finasteride were prepared by dissolving 25 mg of drug in 25 mL of methanol to get 1 mg/mL solutions. Subsequent dilutions of these solutions ranging from 0.2-1 μg/mL of tamsulosin hydrochloride and 2-10 μg/mL of finasteride were made in same 10 mL volumetric flask with mobile phase (acetonitrile and water 60:40 v/v). 20 μL of each concentration was injected into the HPLC systems to obtain the chromatogram.

Calibration curves were constructed of plotting mean peak areas against the corresponding drug concentrations. The detector response was found to be linear in the concentration range of 0.2-0.8 μg/mL for Tamsulosin hydrochloride and 2-20 μg/mL for Finasteride. The linearity plots are given in Fig. 1 and 2. A typical chromatogram has given in Fig. 3.

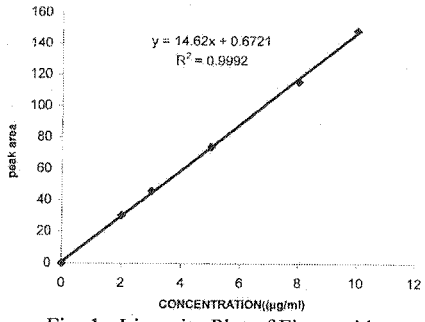


Fig. 1 : Linearity Plot of Finasteride

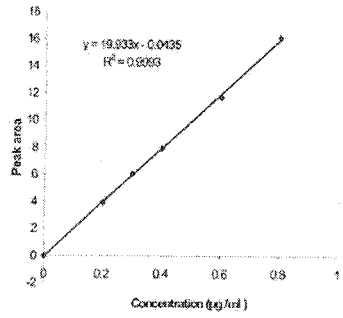


Fig. 2 : Linearity Plot of Tamsulosin

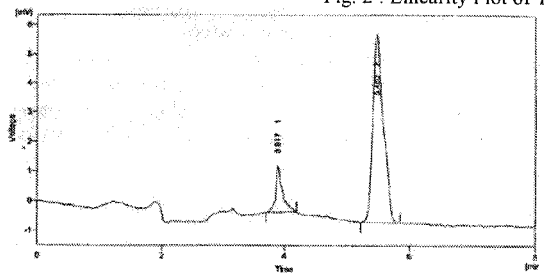

Fig. 3. Typical chromatogram of tmsulosin and finasteride

**Estimation of Finasteride and Tamsulosin Hydrochloride in capsules:** The quantity of formulation containing both drugs equivalent to 4 mg of tamsulosin hydrochloride that is equivalent to 50 mg of finaseride was weighed accurately and taken into 50 mL volumetric flask. Both drugs were extracted into methanol and the volume was adjusted to 50 mL, mixed and filtered. From the filtrate 0.1 mL was pipetted in 25 mL of volumetric flask and then volume was adjusted to 25 mL with mobile phase. 20 μL of this solution was injected into HPLC system to obtain the chromatogram and the concentrations of tamsulosin and finasteride hydrochloride were calculated from the standard graph. The results were given in the Table-2.

**Recovery studies:** Recovery experiments by adding known amount of finasteride and tamsulosin to the previously analyzed samples. The results are given in Table-3.

## RESULTS AND DISCUSSION

The absence of additonal peaks in the chromatogram indicate non-interference of common excipents in the formulations. This method is found to be precise. Validation parameters of the method are given in Table-1. The values of recovery studies are given in Table-3 indicate that the method is accurate. The run time is only 10 min and the flow rate of the mobile phase is 1 mL/min. The method is rapid and economic. The proposed method could be used for routine quailty control analysis of these drugs in combined dosage forms.

TABLE-1
VALIDATION PARAMETERS

| Parameters | FNS | TMS |
|---|---|---|
| Linearity range (μg/mL) | 2-10 | 0.2-0.8 |
| Linearity coefficient | 0.9992 | 0.9993 |
| (%) RSD | 0.56 | 0.78 |
| Resolution factor | 4.221 | - |
| Symmetry factor | 1.28 | 1.109 |
| Efficiency (no of plates) | 3,500 | 2,600 |
| Slope | 14.62 | 19.933 |
| Intercept | 0.6721 | -0.0435 |

TABLE-2
ANALYSIS OF FINASTERIDE AND TAMSULOSIN HYDROCHLORIDE IN DOSAGE FORMS

| Pharmaceutical formulation | Labeled amount (mg) | | Amount found (mg) | | (%) Drug | |
|---|---|---|---|---|---|---|
| | FNS | TMS | FNS | TMS | FNS | TMS |
| Capsule 1 (FINAST-T) | 5 | 0.4 | 4.98 | 0.396 | 99.60 | 99.00 |
| Capsule 2 (URIMAX F) | 5 | 0.4 | 4.96 | 0.397 | 99.20 | 99.25 |

TABLE-3
RECOVERY STUDIES

| Drug content μg/mL | | Conc. of Standard durg added (μg/mL) | | Amount drug found (μg/mL) | | (%) Recovery | |
|---|---|---|---|---|---|---|---|
| FNS | TMS | FNS | TMS | FNS | TMS | FNS | TMS |
| 5 | 0.4 | 0 | 0.0 | 4.952 | 0.396 | 99.01 | 99.00 |
| 5 | 0.4 | 2 | 0.1 | 6.940 | 0.496 | 99.14 | 99.20 |
| 5 | 0.4 | 3 | 0.2 | 8.040 | 0.593 | 100.50 | 98.80 |
| 5 | 0.4 | 5 | 0.4 | 9.950 | 0.797 | 99.50 | 99.62 |

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