Simultaneous Determination of Tamsulosin hydrochloride and Finasteride in Pharmaceutical Formulations Using High Performance Liquid Chromatography

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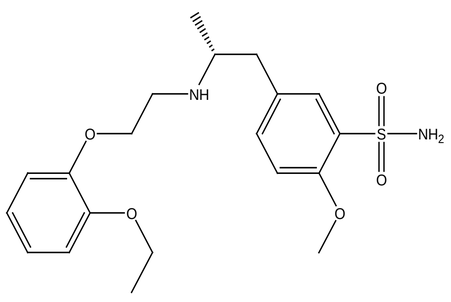
Introduction

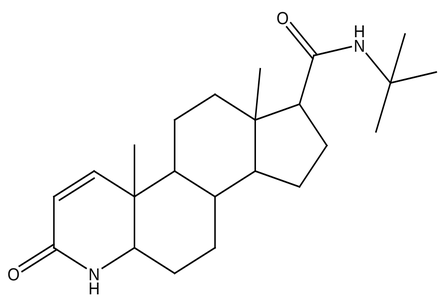
Tamsulosin(5-[(2R)-2-[2-(2-ethoxyphenoxy)ethylamino]propyl]-2-methoxybenzenesulfonamide) and finasteride((1S,3aS,3bS,5aR,9aR,9bS,11aS)-N-tert-butyl-9a,11a-dimethyl-7-oxo-1,2,3,3a,3b,4,5,5a,6,9b,10,11-dodecahydroindeno[5 ,4 -f] quinoline-1-carboxamide) are used for treatment of patients with symptomatic benign prostatic hyperplasia.[1, 2] Combined treatment of a1-adrenoceptor (AR) antagonist and 5α-reductase inhibitor has been suggested to be superior to therapy alone. To simple and fast assay of tamsulosin and finasteride, we developed a simultaneous high-performance liquid chromatographic method with UV- detection. Liquid chromatography was performed on an Kromasil $5C_{18}$ (4.6x250mm, 5㎛), the mobile phase consisted of acetonitrile–35mM potassium phosphate buffer with gradient elution. The run time was 25 min and UV detector was operated at 225 nm. Final analytical method was validated.

Materials



M.W : 408.5
M. F : $C_{20}H_{28}N_2O_5S$

Tamsulosin



M.W : 372.5
M. F : $C_{23}H_{36}N_2O_2$

Finasteride

Analytical condition

LC condition

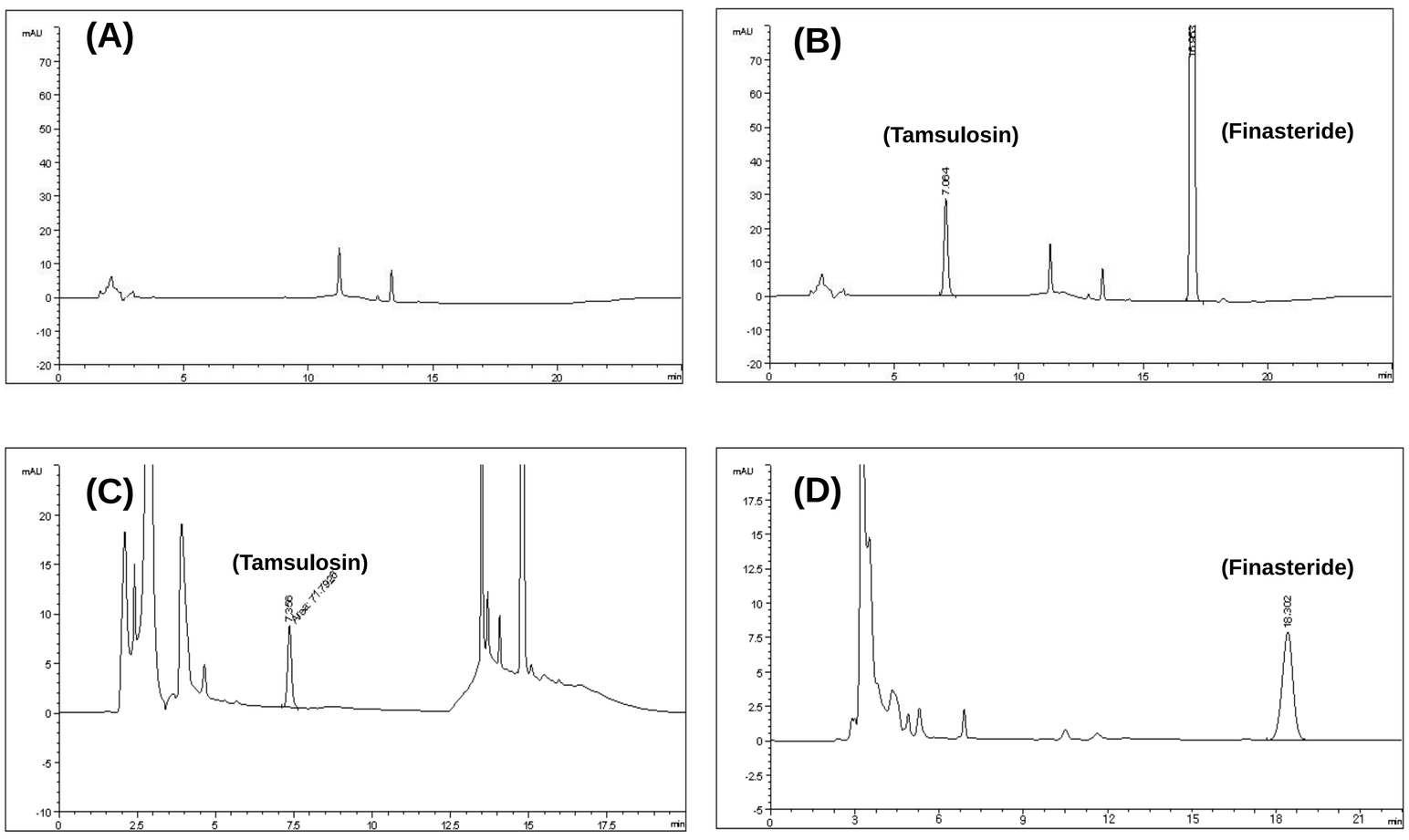
Column	Kromasil $5C_{18}$ (4.6x250mm, 5㎛)	
Column oven temperature	40 ℃	
Mobile phase	35mM potassium phosphate buffer	Acetonitrile
0min	70	30
8min	70	30
10min	50	50
17min	50	50
19min	70	30
25min	70	30
Flow rate	1 ml/min	
Injection volume	200 ul	

Standard preparation

Dilution solvent	20% ethanol	
Target concentration	Tamsulosin (ug/ml)	Finasteride (ug/ml)
	26	650
	23	575
	20	500
	17	425
	14	350

Results

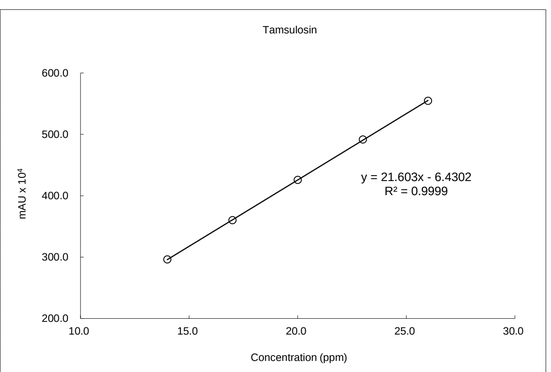
Chromatograms



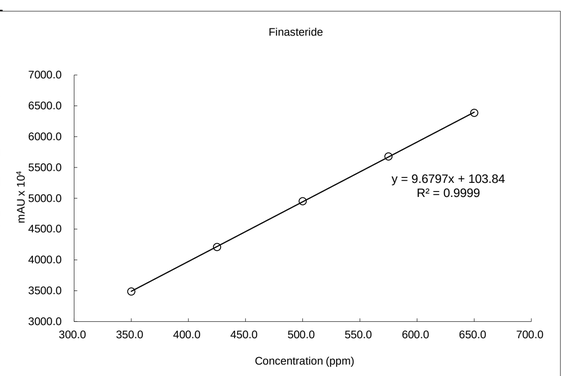
Chromatograms of (A)Blank, (B) Standard, (C) Dissolution sample of Tamsulosin in pH 7.2 and (D) Dissolution sample of Finasteride in water

Linearity

Tamsulosin	
14ug/ml	296.25507
17ug/ml	360.02750
20ug/ml	425.76398
23ug/ml	491.58356
26ug/ml	554.52258
Slope	21.6
Y-intercept	-6.4
R^2	0.9999
SSE	3.3
R	1.0000



Finasteride	
350ug/ml	3489.9514
425ug/ml	4211.3882
500ug/ml	4952.3359
575ug/ml	5678.2930
650ug/ml	6386.3716
Slope	9.7
Y-intercept	103.8
R^2	0.9999
SSE	329.8
R	1.0000



Precision & Accuracy

Table 1

Theoretical concentration (ug/ml)	Area	Precision	Intermediate precision	Accuracy
14	295.9	0.2%	0.0%	100.1%
17	359.9	0.1%	0.1%	
20	424.7	0.3%	0.2%	99.9%
23	491.8	0.1%	0.1%	
26	553.9	0.2%	0.1%	99.8%

Table 2

Theoretical concentration (ug/ml)	Area	Precision	Intermediate precision	Accuracy
350	3487.39	0.1%	0.0%	199.9%
425	4214.35	0.1%	0.0%	
500	4946.57	0.2%	0.1%	100.0%
575	5683.44	0.1%	0.0%	
650	6376.59	0.2%	0.1%	99.8%

Precision and accuracy of Tamsulosin(Table 1) and Finasteride(Table 2)

Conclusions

In this study, simultaneous analytical method of tamsulosin and finasteride was developed. The chromatographic conditions were optimized by studying the effects of temperature of the column and concentration of photassium phosphate buffer. The developed method was found to be selective, sensitive, precise, linear, accurate and reproducible in determining the tamsulosin and finasteride. And this method was applied to analysis of dissolution test for combined formulation drug.

*** Reference**

[1] J. Macek∗, J. Kl´ıma, P. Pt´aˇcek, Rapid determination of tamsulosin in human plasma by high-performance liquid chromatography using extraction with butyl acetate, Journal of Chromatography B, 809 (2004) 307–311

[2] The Merck Index, 13th ed., Merck, Rehway, New York, 2000.

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