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Review Article

Analytical Techniques for the Quantification of Finasteride - A Review

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Abstract

Finasteride is an orally active 5-alpha reductase inhibitor. It is used for the treatment of benign prostatic hyperplasia. It is used for the symptomatic relief during acute urine retention and FDA had approved Finasteride for the treatment of male pattern hair loss in 1998. A brief review of the analytical techniques so far developed for the estimation of Finasteride was discussed in the present study.

Keywords: Finasteride; FDA; Biological Fluids

Introduction

Finasteride is (CAS:98319-26-7) chemically (4aR, 4bS, 6aS, 7S, 9aS, 9bS, 11aR) -N-tert-butyl-4a,6a-dimethyl-2-oxo-1H, 2H, 4aH, 4bH, 5H, 6H, 6aH, 7H, 8H, 9H, 9aH, 9bH, 10H, 11H, 11aH-indeno[5, 4-f]quinoline-7-carboxamide with molecular formula, $C_{23}H_{36}N_2O_2$ and molecular weight 372.5441 g/mole is freely soluble in ethanol and in dichloromethane. Finasteride belongs to 5-alpha reductase inhibitors [1] class. Finasteride (Figure 1) acts by blocking the production of the male hormone that responsible for the enlargement of the prostate. Finasteride is a synthetic 4-azasteroid and also a selective inhibitor of the intracellular enzyme steroid Type II 5α-reductase that converts the androgen testosterone into 5α-di hydro testosterone. Finasteride can be used alone or in combination with other medicines.

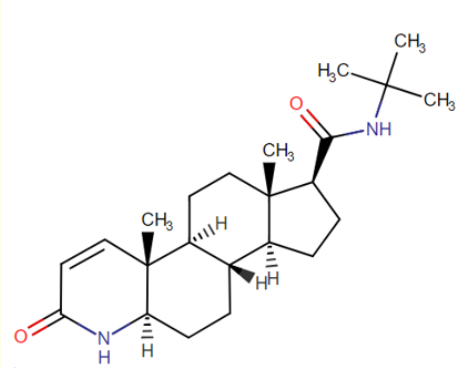

Figure 1: Chemical structure of Finasteride.

Finasteride was estimated by different analytical techniques such as spectrophotometry [2-8], spectrofluorimetry [9], HPLC [10-15] and mass spectrophotometric techniques [16-19] in tablet formulations as well as biological fluids.

Various spectrophotometric methods were developed in different reagents for the estimation of Finasteride. Vijaya Lakshmi., *et al*. developed spectrophotometric method [2] for the estimation of Finasteride using Dichloromethane (λ_{max} 254 nm) and Beer's law was obeyed over the concentration range 5-25 µg/ml. Mukesh Bansal., *et al*. analysed [3] Finasteride tablets using saline phosphate buffer (pH 7.4) and Beer's law was obeyed (λ_{max} 287 nm) over

the concentration range 2-20 µg/ml. Shraddha*., et al.* developed a spectrophotometric method [4] in methanol for the estimation of Finasteride (λ_{max} 255 nm) and Beer's law was obeyed over the concentration range 2-12 µg/ml. Sevgi Tatar Ulu., *et al*. developed spectrophotometric methods [5] for the estimation of Finasteride in tablets basing on the ion-pair complex formation with bromo phenol blue (λ_{max} 409.5 nm), bromo cresol green (λ_{max} 410 nm) and bromo thymol blue (λ_{max} 411 nm) and the linearity was observed over the concentration range 3-15, 3-15 and 5-20 g/ml in bromo phenol blue, bromo cresol green and bromo thymol blue respectively. Sally Mohammed Ahmed and Abdalla Ahmed Elbashir developed a visible spectrophotometric method [6] using sodium 1,2-naphthoquine-4- sulfonate in which Finasteride forms a brown product (λ_{max} 447 nm) in 0.1M disodium hydrogen phosphate buffer solution (pH adjusted to 13.0 with 1M sodium hydroxide). Beer's law was obeyed over the concentration range 2-14 µg/ml. Manish., *et al*. developed a spectrophotometric method [7] in chloroform for the estimation of Finasteride (λ_{max} 245 nm) and Beer's law was obeyed over the concentration range 10-120 µg/ml. Alaa SA and Mohammed AK., *et al*. developed spectrophotometric methods [8] for the estimation of Finasteride in tablets and biological forms and the presence of its oxidative degradants such as potassium permanganate, Cerric sulfate and N-bromosuccinimide with λ_{max} 663, 528 and 520 and the linearity observed was 0.12- 3.84, 0.12-3.28 and 0.14-3.56 respectively. The details of these spectrophotometric methods were summarized in Table 1. Ali Saber Abdelhameed., *et al*. developed a spectrofluorimetric method [9] based on quenching effect of Finasteride on bovine serum albumin in phosphate buffered saline (pH 7.4) and the linearity observed over the concentration range 0.5–15 µg/ml.

Table 1: Spectrophotometric methods.

Reagent	Linearity (µg/ml)	λ_{max} (nm)	Reference
Dichloromethane	5 – 25	254	[2]
Saline phosphate buffer (pH 7.4)	2-20	287	[3]
Methanol	2-12	255	[4]
Bromophenol blue	3-15 x 10^3	409.5	[5]
Bromocresol green	3-15 x 10^3	410	
Bromothymol blue	5-20 x 10^3	411	
1,2-naphthoquine-4- sulfonate	2-14	447	[6]
Chloroform	10 – 120	245	[7]
Potassium permanganate	0.12– 3.84	663	[8]
Cerric sulfate	0.12–3.28	528	
N-bromosuccinimide	0.14 – 3.56	520	

Shraddha*., et al.* developed a RP-HPLC method [10] in acetonitrile: water (60:40, v/v) with flow rate 1.1 mL/min (Detection wavelength 245nm) methanol for the estimation of Finasteride and linearity was observed over the concentration range 2-12 µg/ml. Basavaiah*., et al.* developed a RP-HPLC method [11] in methanol: water (80:20, v/v) with flow rate 1.0 mL/min (Detection wavelength 225nm) for the estimation of Finasteride and linearity was observed over the concentration range 2-30 µg/ml. Sindhura*., et al.* developed a RP-HPLC method [12] using 0.02% formic acid: methanol (20:80, v/v) mixture with flow rate 1.0 mL/min (Detection wavelength 220 nm) for the estimation of Finasteride and linearity was observed over the concentration range 5-50 µg/ml. Akheel*., et al.* developed a stability indicating RP-HPLC method [13] in acetonitrile: water (95:5, v/v) with flow rate 0.7 mL/min (Detection wavelength 210 nm) for the estimation of Finasteride and linearity was observed over the concentration range 20-600 µg/ml. Segall., *et al*. carried out a stability-indicating HPLC method [14] to determine finasteride in a tablet formulation using methanol: water (70: 30, v/v) as mobile phase with flow rate 1.0 mL/min (Detection wavelength 210 nm) and linearity was observed over the concentration range 50-80 µg/ml. Ptacek., *et al*. carried out a stability-indicating HPLC method [15] to determine finasteride in human plasma in presence of an internal standard, Clobazam using acetonitrile and 15 mM potassium dihydrogen phosphate (40:60,

v/v) as mobile phase with flow rate 0.6 mL/min (Detection wavelength 210 nm) and linearity was observed over the concentration range 0.004 to 0.3 µg/ml. The details of these liquid chromatographic methods were summarized in Table 2.

Fang-Qiu Guo., *et al*. developed a LC-ESI-MS method [16] for the determination of Finasteride in human plasma in presence of an internal standard, Clobazam using acetonitrile-water (46:54, v/v), 0.1% acetic acid, and 0.1% tri fluoro acetic acid as mobile phase on a Hypersil-Keystone C18 reversed-phase column and the linearity was observed over the concentration range 0.2-120 ng/ml. Syed Husain., *et al*. developed a LC-ESI-MS method [17] for the determination of Finasteride in human plasma in presence of an internal standard using acetonitrile and 2 mM ammonium formate buffer (58:42; pH was adjusted to 2.5 using formic acid) as mobile phase on a Zorbax Eclipse® C8 analytical column and the linearity was observed over the concentration range 0.1- 60 ng/mL. Prasad., *et al*. developed a UPLC-MS/MS method [18] for the determination of Finasteride in human plasma using 1.0 mM Ammonium Formate Buffer pH 3.0 (adjusted with formic acid) : Acetonitrile (58:42) as mobile phase on a Acquity UPLC BEH C18 column and the linearity was observed over the concentration range 0.1- 30 ng/mL ng/ml. Constanzer., *et al*. developed a HPLC-APCI-MS/MS method [19] for the determination of Finasteride in human plasma and semen using acetonitrile: water containing 0.1% formic acid (70:30) as mobile phase and the linearity was observed over the concentration range 0.2-100 ng/ml. The details of these LC-MS methods were summarized in Table 3.

Table 2: Liquid chromatographic methods.

Liquid chromatographic methods				
Mobile Phase (v/v)	**λ (nm)**	**Column**	**Linearity (µg/ml)**	**Ref**
Acetonitrile: Water (60:40)	245	Agilent 1220	2-12	[10]
Methanol: Water (80:20)	225	ODS RP C18	2.0-30	[11]
0.02% Formic acid: Methanol (20:80)	220	Phenomenex C18	5-50	[12]
Acetonitrile: Water (95:05)	210	Shimpak C8	20-600	[13]
Methanol: Water (70 : 30)	210	C18	50-80	[14]
Acetonitrile: Potassium dihydrogen phosphate (40:60)	210	C18	0.004 - 0.3	[15]

Table 3: LC-MS methods.

Mobile Phase (v/v)	Linearity(ng/ml)	Method	Ref
Acetonitrile: water (46:54), 0.1% acetic acid, 0.1% trifluoracetic acid	0.2 - 120	HPLC-ESI- MS	[16]
Acetonitrile: 2 mM ammonium formate buffer (58:42, pH adjusted at 2.5 using formic acid)	0.1- 60	HPLC-ESI- MS	[17]
1mM Ammonium Formate Buffer pH 3.0 (adjusted with formic acid): Acetonitrile (58:42)	0.1 - 30	UPLC–MS/MS	[18]
Acetonitrile: 0.1% aq formic acid (70:30)	0.2 - 100	HPLC-APCI- MS)	[19]

Conclusion

The present study represents a detailed review of the analytical methods so far developed for the estimation of Finasteride in pharmaceutical formulations as well as biological fluids.

Bibliography

1. Vaughan ED. "Long-term experience with 5-alpha-reductase inhibitors". *Reviews Urology* 5.4 (2003): S28-S33.

2. Vijaya Lakshmi., *et al*. "Development and validation of UV spectrophotometric method for the estimation of Finasteride in tablets". *International Journal of Pharma Sciences* 3.1 (2013): 123-125.

3. Mukesh Bansal., *et al*. "Quantitative determination of Finasteride from tablet formulation by UV-spectrophotometry". *Journal of Pharmaceutical and BioSciences* 1 (2013): 48-50.

4. Shraddha., *et al*. "UV spectrophotometric stability indicating method development and validation for the determination of Finasteride bulk and dosage form". *Journal of Drug Delivery and Therapeutics* 9.4 (2019): 170-172.

5. Sevgi Tatar Ulu. "A new spectrophotometric method for the determination of Finasteride in tablets". *Spectrochimica Acta Part A* 67: (2007): 778–783.

6. Sally Mohammed Ahmed and Abdalla Ahmed Elbashir. "Development and validation of spectrophotometric method for determination of Finasteride in pharmaceutical formulation using 1,2-Naphthoquine-4-sulfonate (NQS)". *Analytical and Bioanalytical Journal of Techniques* 6.247: (2015): 1000248.

7. Manish Kumar T., *et al*. "UV spectrophotometric method for determination of Finasteride in bulk and pharmaceutical dosage form". *International Journal of Pharmacy and Biological Sciences* 1.1 (2011): 39-43.

8. Alaa SA., *et al*. "Optimization and validation of spectrophotometric methods for determination of Finasteride in dosage and biological forms". *Pharmaceutical Methods* 3.1 (2012): 48-55.

9. Ali Saber Abdelhameed., *et al*. "Spectrofluorimetric study of Finasteride and bovine serum albumin interaction and its application for quantitative determination of Finasteride in tablet dosage form". *Analytical Methods* 7 (2015): 5096–5102.

10. Shraddha., *et al*. "Development and validation of a RP- HPLC method for determination of Finasteride in pharmaceutical dosage forms". *World Journal of Pharmaceutical Research* 9.2 (2020): 883-895.

11. Basavaiah K and Somashekar BC. "Determination of Finasteride in tablets by High Performance Liquid Chromatography". *E-Journal of Chemistry* 4.1 (2007): 109-116.

12. Sindhura Manne., *et al*. "Rapid analysis of Finasteride in bulk and formulations by RP-HPLC-PDA method". *Journal of the Chilean Chemical Society* 57.4 (2012): 1469-1471.

13. Akheel A Syed., *et al*. "LC determination of Finasteride and its application to storage stability studies". *Journal of Pharmaceutical and Biomedical Analysis* 25 (2001): 1015-1019.

14. Segall AI., *et al*. "A stability-indicating HPLC method to determine Finasteride in a tablet formulation". *Journal of Liquid Chromatography and Related Technologies* (2020).

15. Ptacek P., *et al*. "Determination of Finasteride in human plasma by liquid–liquid extraction and high-performance liquid chromatography". *Journal of Chromatography B* 738 (2000): 305–310.

16. Fang-Qiu Guo., *et al*. "A rapid, simple, specific liquid chromatographic–electrospray mass spectrometry method for the determination of Finasteride in human plasma and its application to pharmacokinetic study". *Journal of Pharmaceutical and Biomedical Analysis* 43 (2007): 1507–1513.

17. Syed Husain Hashemi Mousavi., *et al*. "A rapid, simple, liquid chromatographic-electrospray ionization, ion trap mass spectrometry method for the determination of Finasteride in human plasma and its application to pharmacokinetic study". *Iranian Journal of Pharmaceutical Research* 11.1 (2012): 59-67.

18. Prasad ., *et al*. "Rapid determination of Finasteride in human plasma by UPLC–MS/MS and its application to clinical pharmacokinetic study". *Journal of Chromatography B* 878 (2010): 1718–1723.

19. Constanzer ML., *et al*. "Picogram determination of Finasteride in human plasma and semen by high-performance liquid chromatography with atmospheric-pressure chemical-ionization tandem mass spectrometry". *Journal of Chromatography B* 658 (1994): 281-287.