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Original Research Article

A concise review- Development of an analytical method and validation of dutasteride

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ABSTRACT

The synthetic 4-azasteroid dutasteride inhibits the type 1 and type 2 isoenzymes of 5-alpha-reductase in a selective and competitive manner. Men with symptomatic benign prostatic hyperplasia (BPH), which is characterized by an enlarged prostate, may use it. Orally administered dutasteride has a 60% bioavailability and is quickly absorbed.

This work focuses on the most recent developments in analytical techniques for quantifying dutasteride in various biological samples (including human plasma), as well as in commercially available dose forms and bulk. High-performance thin-layer chromatography (HPTLC), gas chromatography in conjunction with tandem mass spectrometry (GC-MS), high-performance liquid chromatography (HPLC), and UV spectroscopy will all be thoroughly examined in this review. The matrix, stationary phase, mobile phase composition, detection wavelength, RF value, retention duration, detection limit (DL), carrier gas, and flow rate are just a few of the characteristics that will be covered.

1. Introduction

Type 1 and type 2 variants of the 5α-reductase enzyme, which converts testosterone into 5α-dihydrotestosterone (DHT), are specifically inhibited by dutasteride. Given that DHT is crucial in prostate enlargement, dutasteride is employed to treat benign prostatic hyperplasia, a condition frequently affecting men over the age of 50.[1]

5-α, 17β)-N-{2,5-bis (trifluoromethyl)phenyl}-3-oxo-4-azaandrost-1-ene-17-carboxamide is the chemical name for dutasteride (DTS). C27H30F6N2O2 is its empirical formula, and its molecular weight is 528.5 grams per mole.[2]

Dutasteride is an intracellular enzyme that transforms testosterone; it is used to treat patients with benign prostatic hyperplasia who exhibit symptoms.Dutasteride belongs to the class of 5α-reductase inhibitors, which selectively and competitively block both type 1 isoforms (active in sebaceous glands across various skin areas and the liver) and type 2 isoforms (primarily located in reproductive tissues like the prostate, hair follicles ,seminal vesicles, epididymides and liver).[3,4]

A review of the literature shows that numerous analytical and bioanalytical techniques have been developed for analyzing dutasteride. These techniques, which can be applied alone or alongside other medications, include high-performance liquid chromatography (HPLC).[5–7]Dutasteride dissolves well in organic solvents such as methanol, dimethyl sulfoxide, ethanol, acetone, and isopropanol but is nearly insoluble in water. The USP Medicines Compendium lists it as a medication only meant for monograph development. It works by preventing testosterone from being converted to 5α-dihydrotestosterone.

After being approved by the USFDA in October 2002, it has subsequently been granted authorization in a number of other nations. DHT is the primary androgen responsible

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for the initial growth and subsequent enlargement of the prostate gland.[8,9]

1.1. Structure

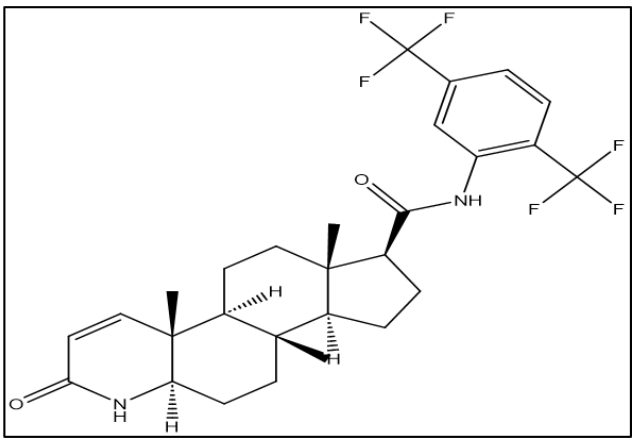

Figure 1: Dutasteride structure

2. Pharmacodynamic Profile

Dutasteride's effect on 5α-reductase inhibition has been investigated in lab settings. However, research on how dutasteride affects levels of dihydrotestosterone (DHT), testosterone, luteinizing hormone (LH), and prostate-specific antigen (PSA) has predominantly been conducted with volunteers or patients suffering from benign prostatic hyperplasia (BPH)[10,11] The effects of dutasteride on spermatogenesis, lipid levels, and bone metabolism have also been examined in volunteer studies.[12]

2.1. Activity that inhibits 5α-reductase

The 4-azasteroid dutasteride is a very strong and selective inhibitor of type 1 and type 2 5α-reductase.Top of FormBottom of Form In laboratory studies, its inhibition constants (Ki) are 6 nmol/L for type 1 5α-reductase and 7 nmol/L for type 2 5α-reductase.[10,11] Dutasteride operates about five times faster and is 45 times more potent in inhibiting type 1 5α-reductase than finasteride, which has a Ki of 360 nmol/L. Additionally, for inhibiting type 2 5α-reductase, dutasteride is estimated to be 2.5 times more potent than finasteride.[11,13,14]

2.2. Impact on DHT and other hormone levels

The impact of dutasteride on serum hormone levels has been studied through three randomized, placebo-controlled, dose-ranging trials involving male volunteers or patients with benign prostatic hyperplasia (BPH). Dutasteride administration led to increases in luteinising hormone and androstenedione, but these changes were considered not clinically significant.[15–17] In the single-blind study with 48 volunteers, participants were administered a single dose of either dutasteride (between 0.01 and 40 mg), finasteride 5 mg, or a placebo. In contrast, the double-blind studies, which included patients with a prostate volume of at least 30 mL or an International Prostate Symptom Score (IPSS) of 8 or higher, had durations of 4 weeks (with 53 participants) or 24 weeks (with 399 participants)[17]

Dutasteride caused dose-dependent decreases in average DHT levels in both volunteers and patients who took the drug daily for 4 or 24 weeks. Reductions in DHT levels generally stabilized at doses above 0.5 mg, which is the recommended dosage. After a single dose of dutasteride ranging from 1 to 40 mg, DHT levels in volunteers were significantly reduced by 72–95% compared to baseline (all $p \leq 0.001$ versus placebo For patients who received daily doses of dutasteride ranging from 0.05 to 5 mg for 24 weeks, DHT levels were reduced by 52.9–98.4% from baseline (all $p < 0.001$ versus placebo)[16,17]

3. Impact on PSA Levels

PSA levels declined after treatment with dutasteride.[18,19] In an individual analysis of one of the ARIA trials (n = 674), the mean baseline levels of total and free PSA in patients receiving dutasteride were 4.4 and 0.9 ng/mL, respectively. After 12 months of treatment, these levels were reduced by an average of 45.7% and 55.5%.[19] In contrast, with placebo, total PSA levels increased by an average of 8.4%, rising from 4.1 ng/mL at baseline, and free PSA levels increased by an average of 14.0%, rising from 0.9 ng/mL at baseline. The free-to-total PSA ratio followed a similar pattern, decreasing by an average of 6.7% in patients receiving dutasteride and increasing by an average of 6.7% in those receiving placebo.[19]

4. Pharmacokinetic Profile

As of February 2006, there were no published pharmacokinetic studies specifically focused on dutasteride; all the data reviewed were obtained from the manufacturer's prescribing information. Generally, the pharmacokinetic data available were mostly from studies involving healthy volunteers.[20]

4.1. Absorption

Dutasteride is rapidly absorbed and shows dose-proportional increases in mean maximum plasma concentrations (Cmax) after oral administration. Its bioavailability is approximately 60% when taken orally.[21] Following the administration of dutasteride in doses ranging from 0.1 to 40 mg, the absorption lag time (tlag) was 0.32 hours, as determined by the two-compartment model.[10]

4.2. Distribution

Food intake decreases the maximum serum concentrations of dutasteride, though this reduction is not deemed clinically significant. Once in the bloodstream, dutasteride is extensively bound to albumin (99%) and alpha-1 acid glycoprotein (96.6%) and is broadly distributed throughout both central and peripheral compartments and has a substantial volume of distribution, ranging between 300 and 500 liters.The drug also distributes to semen, where its concentration is about 10% of the serum concentration.[22]

4.3. Metabolism

Dutasteride is extensively metabolized, mainly by the CYP3A4 and CYP3A5 enzymes.[22] Dutasteride undergoes extensive metabolism and is mainly excreted in the feces. At steady state, approximately 5.4% (with a range of 1.0% to 15.4%) of the 0.5 mg/day dose of dutasteride is excreted in the feces as unchanged drug.[23]

4.4. Elimination

The elimination of dutasteride is dose-dependent and is best characterized by a combination of linear and nonlinear pathways functioning concurrently. At high plasma concentrations of dutasteride (daily doses greater than 1 mg), the linear pathway becomes the primary route of elimination, leading to a clearance rate of 0.58 L/h.[10]

4.5. Analytical accounts on Dutasteride

The thorough literature analysis identified a number of analytical techniques, such as UV spectrophotometry, HPLC, HPTLC, and LC-MS/MS, for detecting dutasteride in both bulk materials and pharmaceutical formulations. These techniques describe how to analyze dutasteride in matrices like human plasma and in various dose forms, including tablets.

5. Spectrophotometric Overview

5.1. UV-Visible spectroscopy method

Mohammad Kaisarul Islam et. al. outlined a simple visible spectrophotometric technique for measuring Dutasteride in both raw materials and pharmaceutical formulations.Top of FormBottom of FormThe linearity of the method was assessed across seven concentration levels, and in the concentration range of 12 μg/ml to 28 μg/ml, Beer's law was followed. It was discovered that the correlation coefficient (r) for the standard curve was 0.997. In pharmaceutical formulations, the percentage recovery of dutasteride varies between 100% and 101%.employing a spectrophotometer with a blank of a 50:50 methanol:water mixture and a wavelength range of 200–380 nm. Dutasteride's absorption curve showed a clear absorption maximum at 241 nm.[24]

Mahtab Ali et. al. presented a simple visible spectrophotometric method for quantifying dutasteride in both bulk materials and pharmaceutical products. A linear relationship between absorbance and concentration was demonstrated by the calibration curves, and Beer's law was followed over a concentration range of 5-100 μg/mL. The correlation coefficient (r) for the standard curve was 0.9998. The recovery percentages for the dutasteride stock solution and the dosage form solution were 99.79% and 100.00%, respectively.[25]

Vishnu P. Choudhari et. al.described a straightforward visible spectrophotometric technique for analyzing dutasteride in both bulk quantities and pharmaceutical dosage forms. The first technique involves measuring derivative amplitudes at certain wavelengths and is referred to as the first-order derivative spectroscopy method (Method A). Area Under the Curve Spectrophotometry (Method B) is the second technique. In the first-order derivative spectra, amplitudes at 247.67 nm were chosen for determining DUTA, while the wavelength range of 237.13-238.25 nm was selected for DUTA determination using the AUC method in methanol. Beer's law is applicable to DUT A in Method A within a concentration range of 10–50 μg/mL, while it is applicable to DUTA in Method B within a range of 5–25 μg/mL. The recovery rate for DUTA using the first-order derivative spectroscopic method ranged from 99.60% to 99.99%. The recovery for DUTA using the AUC method ranged from 99.30% to 101.12%.[26]

AVVNKS Kumar et. al. developed four straightforward and sensitive visible spectrophotometric methods for the assay of dutasteride. Method I is based on the interaction of an acetonitrile solution with dutasteride, an electron donor, and chloranil, a π-acceptor. A reddish-orange chloranil radical anion is produced by this reaction, and its peak absorption occurs at 525 nm.In Method II, ferric chloride and an acidic environment are used to drive an oxidative coupling reaction between dutasteride and 3-methyl-2-benzothiazolinone hydrazone hydrochloride. The result of this reaction has a green hue with a peak absorption at 550 nm.The creation of ion couples between dutasteride and the dyes bromothymol blue and bromophenol blue is required for Methods III and IV. After the ion pairs are extracted into chloroform, absorption maxima for bromothymol blue and bromophenol blue are found at 425 and 435 nm, respectively. Regression analysis of the Beer's law plots showed a strong correlation within the concentration ranges of 2-40 μg/mL for Method I, 1-20 μg/mL for Method II, 5-50 μg/mL for Method III, and 2-20 μg/mL for Method IV.[27]

Kareem, Z. M et. al. introduced a novel spectrophotometric flow injection method for measuring Dutasteride (DS) in both its pure form and in pharmaceutical tablet formulations. This procedure is predicated on the way that dutasteride, an electron donor, and chloranil, an acceptor, interact with acetonitrile. A reddish-orange

Table 1: UV-Visible Spectroscopy method for analysis of dutasteride

Sr. No.	Drug	Matrix/ Dosage form	Solvent		Detection (nm)	Linearity (ug/ml)	Ref. No.
1	Dutasteride	Tablet	methanol-water (50:50)		241 nm	12-28 μg/ml	24
2	Dutasteride	Tablet	Water,Ethanol, Methanol,Polyet Hylene glycol		242 nm	5-100 μg/mL	25
3	Dutasteride	Tablet /Capsule	methanol		(Method A) -247.67 nm	10-50 μg/mL	26
					(Method B) -237.13 nm	5-25 μg/mL	
4	Dutasteride	Tablet	Method-I	500 mg Chloranil in 100ml of acetonitrile	525 nm	2-40 μg/mL	27
			Method-II	3-methyl-2-benzothiazolinone hydrazone hydrochloride in the presence of ferric chloride	550 nm	1-20 μg/mL	
			Method-III	bromothymol blue and bromophenol blue	425 nm	5-50 μg/mL	
			Method- IV		435 nm	2-20 μg/mL	
5	Dutasteride	Tablet	500 mg Chloranil and 100 ml acetonitrile		525 nm	0.9948-8.932 μg/mL	28

Chloranil radical anion is produced by this reaction, and its peak absorption occurs at 525 nm. The technique exhibits linearity with a correlation coefficient of 0.9969 over a concentration range of 0.9948 to 8.932 μg/mL. It has a relative standard deviation (RSD) of 0.422% and a detection limit of 0.420 μg/mL.[28]

5.2. Chromatographic overview

5.3. HPLC method

Taraka Ramesh G et. al. outlined a stability showing RP HPLC method for the estimation of dutasteride in tablet dosage formRP-HPLC separation was carried out in isocratic mode using a Symmetry C18 column (4.6 x 250 mm, 5μm, XTerra brand). The mobile phase was composed of 80% HPLC-grade acetonitrile and 40% phosphate buffer with the pH adjusted to 3.0 using orthophosphoric acid. A DAD detector was used for detection at 280 nm, and the flow rate was kept constant at 1.0 mL per minute. The entire run took place in 8 minutes. Dutasteride had a retention time of approximately 2.2 minutes.[29]

Abhilasha V.Deshmukh et. al. outlined a stability showing RP HPLC method for the estimation of armodafinil in tablet dosage form. Using a BDS HYPERSIL C18 (4.6 mm × 250 mm) analytical column, the method's development aimed to provide an accurate, dependable, and robust RP-HPLC approach for the quantitative determination of Dutasteride (DTS) in bulk materials and single-component formulations. The mobile phase included a 75:10:15 (V/V/V) ratio of acetonitrile, water, and methanol, a flow rate of 0.7 mL/min, and UV detection at 274 nm. Dutasteride was effectively resolved and eluted at 8.34 minutes, with a total run time of 10 minutes and the column temperature maintained at 20°C.[30]

G. Sravan Kumar Reddy et. al.described a stability-indicating RP-HPLC method for quantifying dutasteride in tablet dosage forms. A Symmetry C18 column (4.6 x 150 mm, 5 μm, XTerra brand) was used in isocratic mode for the RP-HPLC separation. 20% phosphate buffer, pH-adjusted to 2.5 with orthophosphoric acid, and 80% acetonitrile (HPLC grade) made up the mobile phase. Detection was done at 274 nm while the flow rate was kept at 0.8 mL per minute.Dutasteride exhibited a retention time of 2.003 minutes.[31]

Dr. Jadhav S. B et. al. developed a stability-indicating RP-HPLC method for the quantification of dutasteride in tablet dosage forms. A Phenomenex C18 column (250 mm x 4.6 mm, 5 μm particle size) was used as the stationary phase for the separation. The mobile phase was an 80:20 v/v mixture of methanol and water that was utilized in an isocratic mode at a flow rate of 1.0 mL/min. The retention period for dutasteride was 2.94 minutes. For drug concentrations between 1 and 5 μg/mL, the procedure showed linearity (r2 = 0.9999). In the investigation on forced degradation, dutasteride degraded 16.82% after three hours in 0.1 N HCl. The alkaline degradation study resulted in an 11.85% degradation, while the overall observed degradation for dutasteride was 4.10%.[32]

Ch Maratha Martini et. al. developed a stability-indicating RP-HPLC method for estimating dutasteride in tablet dosage forms. A Kromasil C18 column (150 mm × 4.6 mm, 5 μm particle size) was used for the isocratic method of chromatographic separation, and the mobile phase consisted of phosphate buffer and acetonitrile mixed

30:70 (v/v). Dutasteride showed a retention time of 7.2 minutes when the eluents were detected at 242 nm. A flow rate of 0.8 mL/min was selected. The method showed linearity for dutasteride concentrations ranging from 0.25 to 1.5 μg/mL, with a correlation coefficient of 0.999.

Dr. Keerthana Diyya et. al. developed a stability-indicating RP-HPLC method for estimating dutasteride in tablet dosage forms. An XTerra C18 column (150 × 4.6 mm, 5 μm particle size) was used as the stationary phase to produce the separation. Ammonium dihydrogen phosphate buffer (pH 6.5) and methanol were combined in an isocratic mobile phase at a flow rate of 1.0 mL/min in a 25:75 ratio. A UV detector was used to carry out the detection at 246 nm. The dutasteride retention time under these ideal circumstances was 4.26 minutes. Regression analysis revealed a good correlation (R^2 = 0.999) between 1.25 and 7.5 μg/mL for dutasteride, indicating that the approach was linear. The percentage recovery of dutasteride from the pharmaceutical dosage form was found to be 99.23%.[33]

Syed Hafeez Ahmed et. al.developed a stability-indicating RP-HPLC method for quantifying dutasteride in tablet dosage formsAn Inertsil ODS 3V C18 column (150 x 4.6 mm, 5 μm) was used for the chromatographic separation. Thirty liters each of acetonitrile, methanol, and 20 mM ammonium acetate buffer (pH 3.5) made up the mobile phase. Detection was performed at 223 nm. The method showed linearity for dutasteride concentrations ranging from 24 to 56 μg/mL, with a correlation coefficient (r^2) of 0.998.[34]

Patel Virendra Kumar et. al. describe RP-HPLC as an innovative analytical method suitable for detecting dutasteride in both pharmaceutical formulations and bulk drug substances. The goal in developing this technique was to establish a reliable and precise RP-HPLC method using a Shiseido C18 analytical column for accurately measuring the concentration of dutasteride in both bulk and single-component forms. MeOH, ACN, and H2O were combined in a 75:10:15 (V/V/V) ratio to form the mobile phase. A constant flow rate of 0.7 mL/min was employed for detection, and the UV wavelength was set at 274 nm. Dutasteride had a retention time of 8.34 minutes. The calibration plot displayed a linear correlation within the concentration range of 10 to 22 ppm.

Vaishali A. Shirsat et. al. developed a novel, simple, and sensitive reverse phase high-performance liquid chromatography (RP-HPLC) method for performing forced degradation studies on dutasteride. On a Hi-Q Sil C18HS column, DTS and its degradants were separated using a linear gradient elution, and UV detector detection was employed. The mobile phase for the isocratic mode of DTS separation from its degradants was a 20:80 (v/v) mixture of methanol and 10 mM ammonium acetate buffer (pH 4.5).The mobile phase in the linear gradient mode was composed of methanol and 10 mM ammonium acetate (pH 4.5), with the following composition changes: For the first two minutes, split the ratio 50:50; after two minutes, switch to 20:80; after twenty minutes, go back to 50:50; and after thirty minutes, stay at 50:50. A UV wavelength of 225 nm was used for detection, and the flow rate was set at 1.2 mL/min. The elution time for DTS was determined to be 27.438 minutes. Dutasteride's breakdown products were found when it was hydrolyzed in an acidic and alkaline solution. 1.0 mg/mL of 1M HCl was used to perform the acid and alkaline breakdown of DTS. The decomposition was conducted under reflux conditions at 80°C, with the acid decomposition lasting 8 hours and the alkaline decomposition lasting 4 hours.[35]

Kattempudi Paljashuva et. al. developed a stability-indicating RP-HPLC method for quantifying dutasteride in tablet dosage formsA Shimadzu HPLC system with an Agilent C18 column (250 x 4.6 mm, 5 μm) was used to achieve separation. Methanol and water were combined in the mobile phase in a 50:50 (v/v) ratio. At a flow rate of 1.0 mL/min, the analysis was carried out, and a PDA detector operating at 280 nm was used for detection. Dutasteride had a retention time of 2.623 minutes. The method demonstrated linearity for dutasteride concentrations ranging from 10 to 50 μg/mL, with a correlation coefficient of 0.999.[36]

Kudupudi Chandrasekhar et. al. developed a stability-indicating RP-HPLC method for quantifying armodafinil in tablet dosage forms. A Kromasil C18 column (250 x 4.6 mm, 5 μm) with a reverse phase isocratic elution was used to produce the separation. With a flow rate of 1.0 mL/min, the mobile phase was composed of 65% acetonitrile and 35% phosphate buffer. A PDA detector operating at 225 nm was used for the detection. The retention time of armodafinil was 12.914 minutes. The method exhibited linearity for armodafinil concentrations ranging from 25 to 75 μg/mL, with a correlation coefficient of 0.999.[37]

S.C. Rajesh et. al. outlined a stability-indicating RP-HPLC method for analyzing armodafinil in capsule dosage forms. Methanol and a 100 mM dipotassium hydrogen phosphate buffer (pH 9.5) were combined in a 20:80 (% v/v) ratio to form the mobile phase. The analysis was carried out using a Dionex C18 column (250 × 4.6 mm, 5 μm) with a 20 μL injection volume, and the flow rate was kept at 1.2 mL/min. A PDA detector was used to detect the signal at 295 nm, and the retention period was 2.880 minutes. The approach showed linearity with a correlation coefficient of 0.9993 for armodafinil concentrations between 50 and 150 μg/mL. The percentage recovery of armodafinil was found to be 98.53%.[38]

Devanna N et. al. developed a stability-indicating RP-HPLC method for quantifying dutasteride in tablet dosage forms. A 5 μm particle size, 250 mm × 4.6 mm Xterra C18 column was used for the RP-HPLC separation. Acetonitrile, phosphate buffer (pH 6.5), and water were combined in a 75:15:10 (v/v/v) ratio to create the mobile phase.

Table 2: HPLC method for analysis of Dutasteride

Sr. No	Drug	Matrix/ Dosage form	Stationary Phase	Mobile Phase	Detection (nm)	Flow Rate (ml/min)	Retention Time (minutes)	Detector	Ref. No.
1	Dutasteride	Tablet	C18 column (XTerra model, 4.6 x 250 mm, 5 μm)	phosphate buffer with acetonitrile in a 40:80 (% v/v) ratio	280 nm	1.0 ml/min	2.2 minutes	DAD detector	29
2	Dutasteride	Tablet	4.6 mm × 250 mm analytical column, BDS HyperSIL C18	Acetonitrile: Water: Methanol in a 75:10:15 (V/V/V)	274 nm	0.7 ml/min	8.34 minutes	UV detector	30
3	Dutasteride	Tablet	C18 column (XTerra model, 4.6 × 150 mm, 5 μm)	Phosphate buffer and acetonitrile in a 20:80 (v/v) ratio	274 nm.	0.8 ml/min	2.003 minutes	UV-PDA detector	31
4	Dutasteride	Tablet	Column Phenomenex C18 (250 mm × 4.6 mm, particle size 5 μm)	methanol and water in an 80:20 (v/v) ratio	264 nm	1.0 ml/min	2.94 minutes	UV detector	32
5	Dutasteride	Tablet	5 μm particle size, 150 mm × 4.6 mm Kromasil C18 column	Mixed phosphate buffer and acetonitrile in a 30:70 (% v/v) ratio	242 nm.	0.8 ml/min	7.2 minutes	UV detector	33
6	Dutasteride	Tablet	XTerra C18 column (size: 150 x 4.6 mm; particle size: 5 μm)	ammonium dihydrogen phosphate buffer (pH 6.5) and methanol in a 25:75 (% v/v) ratio	246nm	1.0 mL/min	4.26 minutes	UV detector	34

Continued on next page

Table 2 continued

7	Dutasteride	Tablet	3V column of inertsil ODS, C18 (150 x 4.6 ID) 5μm	20 mM ammonium acetate buffer, acetonitrile, with methanol in a 40:30:30 (% v/v/v) ratio	223 nm.	1.0 ml/min	-	UV detector	35
8	Dutasteride	Tablet	Shiseido C18	MeOH, ACN, and H2O in a 75:10:15 (v/v/v) ratio	274 nm	0.7 ml/min	8.34 minutes	UV detector	36
9	Dutasteride	Tablet	Hi-Q Sil C18HS column	ammonium acetate buffer (pH 4.5) and methanol in a 20:80 (v/v) ratio	225 nm	1.2 mL/min	27.438 minutes	UV detector	37
10	Dutasteride	Tablet	Agilent C18 column (size: 250 x 4.6 mm; particle size: 5 μm)	methanol and water in a 50:50 % (v/v) ratio	280 nm	1.0 mL/min	2.623 minutes	PDA detector	38
11	Dutasteride	Tablet	Kromasil C18 column (250 × 4.6 mm, 5 μm particle size)	phosphate buffer and acetonitrile in a 35:65 % (v/v) ratio	225 nm	1.0 mL/min.	12.914 minutes	PDA detector	39
12	Dutasteride	Capsule	5 μm particle size in a 250 × 4.6 mm Dionex C18 column	Methanol to buffer (100 mM dipotassium hydrogen phosphate) in a 20:80 % (v/v) ratio	295 nm	1.2 mL/min	2.880 minutes	PDA detector	40

Continued on next page

Table 2 continued

13	Dutasteride	Tablet	Column XterraC18 (250mmL×4.6mmI.D×5μ)	acetonitrile: phosphate buffer (pH-6.5): water 75:15:10 % (v/v/v)	245 nm	0.8 ml/min	4.3 minutes	-	41
14	Dutasteride	Tablet	Chromosil C18 column (size: 250 mm x 4.6 mm; particle size: 5 μm)	methanol, acetonitrile, and 2% o-phosphoric acid in a 60:20:20 % (v/v/v) ratio	234 nm	1.0 mL/min	5.19 minutes	-	42
15	Dutasteride	Tablet	Phenomenex C18 column (Torrance, CA, USA)	Methanol and 0.02 M ammonium acetate buffer in an 85:15 % (v/v) ratio	274 nm	1.0 mL/min	5.22 minutes	PDA detector	43
16	Dutasteride	Tablet	C18 column (250 x 4.6 mm, particle size: 5 μm)	ACN and water in a 90:10 % (v/v) ratio	292 nm	1.0 mL/min	2.8 minute	PDA detector	44

The separation was carried out at room temperature with a flow rate maintained at 0.8 mL/min. The retention period for dutasteride was 4.3 minutes. UV detection at 245 nm was used to quantify, and peak area analysis was used for the analysis. Linear calibration curves were established for dutasteride concentrations ranging from 10 to 50 μg/mL.[39]

P. Nagaraju et. al. developed a stability-indicating RP-HPLC method for quantifying dutasteride in tablet dosage forms. A Chromosil C18 column (250 mm × 4.6 mm, 5 μm) was used for the separation, and a UV detector was used for detection at 234 nm. Methanol, acetonitrile, and 2% o-phosphoric acid were combined in a 60:20:20 (v/v/v) ratio to form the mobile phase. Dutasteride had a 5.19-minute retention period, and the flow rate was kept at 1.0 mL/min. The calibration plots demonstrated a linear relationship (r = 0.999) for dutasteride concentrations ranging from 20 to 120 μg/mL.[40]

D.B. Patel et al. presented a validated stability-indicating HPLC method for quantifying dutasteride in pharmaceutical dosage forms. A Phenomenex (Torrance, CA, USA) C18 column was used for the HPLC process, and the mobile phase consisted of 15% ammonium acetate buffer (0.02 M) and 85% methanol (pH 9.5, corrected with triethylamine). Photodiode array (PDA) detection at 274 nm was used for quantification, with the flow rate set at 1.0 mL/min. Dutasteride had a 5.22 minute retention period. The method covered a concentration range of 1–20 μg/mL, with the mean recovery of dutasteride being 99.94 ± 0.611%.[41]

K. Vanitha Prakash et. al. dyeveloped a stability-indicating RP-HPLC method for measuring dutasteride in tablet formulations. The Waters LC setup (Waters, Milford, MA, USA) with a Waters C18 column (250 × 4.6 mm, 5 μm) was used by the HPLC system. The mobile phase used in the analysis was a 90:10 volume/volume combination of water and acetonitrile. A Waters model 2998 photodiode array detector and a Waters model 717 Plus auto sampler were also incorporated in the system. Empower Pro software (Waters, Milford, MA, USA) was used for data analysis. The analytes were found at 292 nm when the mobile phase was pumped at a flow rate of 1.0 mL/min. The method's linearity was evaluated for DTA within a concentration range of 50-150 μg/mL, with correlation coefficients of r = 0.9993 for DTA and r = 0.9997 for another analyte.[42]

5.4. HPTLC method

D.B. Patel et. al. described a stability-indicating HPTLC method for estimating dutasteride in bulk and tablet formulationsThe plates used in the stationary phase had aluminum foil backing and were covered in 0.2 mm layers of silica gel G60F254. Toluene, methanol, and triethylamine were combined in the mobile phase at a 9:1.5:1 (v/v/v) ratio. Densitometric scanning was conducted at 280 nm using a Camag TLC scanner III with a deuterium lamp. Dutasteride produced a distinct band with an Rf value of 0.65. A strong linear relationship (r^2 = 0.9954) was observed between the peak area and concentration over the range of 20-2000 ng/spot, as determined by linear regression analysis.[41]

S.S. Kamat et. al. detailed a stability-indicating HPTLC method for estimating dutasteride in bulk and capsule formulations. The analysis used silica gel 60 F254 as a normal phase stationary phase and toluene, ethyl acetate, and acetic acid in a 7:3:0.5 (v/v/v) ratio for the mobile phase. The UV wavelength used for detection was 210 nm. Calibration curves demonstrated linearity over the range of 50-500 μg/mL, with an R^2 value greater than 0.998.[43]

Sunil R. Dhaneshwar et. al. described a stability-indicating HPTLC method for quantifying dutasteride in bulk and tablet formulations. The mobile phase for the analysis consisted of toluene, methanol, dichloromethane, and triethylamine in a 6:1:1:0.6 (v/v) ratio. The stationary phase used in the analysis was silica gel 60 F254. At 247 nm, a densitometric analysis of the divided zones was carried out. Linear regression analysis (r^2 = 0.995) demonstrated good linearity across the concentration range of 500–1000 ng per band for dutasteride, with a retention factor (Rf) of 0.65.[44]

Dipti B. Patel et al. developed a stability-indicating HPTLC method for estimating dutasteride in bulk and tablet formulations. Utilizing aluminum plates precoated with silica gel G60F254 as the stationary phase, thin-layer chromatography was carried out. In a 9:2:1 (v/v/v) ratio, toluene, methanol, and triethylamine made up the solvent system. With an Rf value of 0.71 ± 0.01 for dutasteride, this approach generated separate spots. At 274 nm, densitometric measurement was carried out in absorbance mode.Linear regression analysis indicated excellent linearity (r^2 = 0.9989) for the peak area across the concentration range of 200–3000 ng per spot.[45]

Mina Wadie et. al. developed a stability-indicating HPTLC method to estimate dutasteride in both bulk and tablet forms. Normal HPTLC silica gel 60 F254 aluminum plates (Merck, Darmstadt, Germany) were used as the stationary phase in the chromatographic separation. The ratio of ethyl acetate to ethanol to ammonia was 9:1:0.2 in the mobile phase.Dutasteride had a retention factor (Rf) of 0.78. The intensities of the drug spots were measured using ImageJ software across concentration ranges from 3 to 35 mg per band. Densitometric analysis of dutasteride was carried out in absorbance mode at 254 nm.[46]

6. Liquid chromatography - Mass Spectrometry

Sudhir S. Kamat et. al. developed a stability-indicating LC–MS method for analyzing dutasteride in capsule formulations. A 150 mm x 4.6 mm C18 column was used in the chromatography, and a flow rate of 1.0 mL/min was employed in the mobile phase, which consisted of

Table 3: HPTLC method for analysis of Dutasteride

Sr. No.	Drug	Matrix/ Dosage Form	Stationary Phase	Mobile Phase	Detection (nm)	Rf	Linearity Range	Ref. No.
1	Dutasteride	Tablets	plates backed with aluminum foil and covered in 0.2 mm silica gel G60F254 layers	toluene, methanol, with triethylamine in a 9:1.5:1 % (v/v/v) ratio	280 nm	0.65	20-2000 ng/spot	43
2	Dutasteride	Capsule	silica gel 60 F254 normal phase	Toluene ,ethyl acetate with acetic acid 7:3:0.5 % (v/v/v)	210 nm	-	50-500 μg mL^{-1}	45
3	Dutasteride	Tablets	F254 silica gel 60	toluene, methanol, dichloromethane with triethylamine in a 6:1:1:0.6 % (v/v) ratio	247 nm	0.65	500–1000 ng per band	46
4	Dutasteride	Tablets	Pre-coated aluminum plates with silica gel (G60F254)	toluene, methanol with triethylamine in a 9:2:1 % (v/v/v) ratio	274 nm	0.71	200–3000 ng per spot	47
5	Dutasteride	Tablets	aluminum plates covered with 60 F254 silica gel	ethyl acetate, ethanol with ammonia in a 9:1:0.2 % (v/v/v) ratio	254 nm	0.78	3-35 mg/band	48

Table 4: LC-MS method for analysis of Dutasteride

Sr. No.	Drug	Matrix/ Dosage Form	Stationary Phase	Mobile Phase	Detection (nm)	Flow Rate (ml/min)	Ret. Time (min.)	Ref. No.
1	Dutasteride	Capsule	C18 column, 150 mm by 4.6 mm	acetonitrile and water combined in a 60:40 % (v/v) ratio	210 nm	1.0 mL/min.	10 minutes	49
2	Dutasteride	Human plasma	Hypurity C18 column with an internal diameter of 50 × 4.6 mm and a particle size of 5 μm	10 mM ammonium formate with acetonitrile in a 20:80 % (v/v) ratio	-	0.6 mL/min	2.5 minutes	50
3	Dutasteride	Human plasma	50 mm × 2.0 mm, 3 μm particle size, Gemini C-18 column	methanol with ammonium formate in a 97:3 (v/v) % ratio	-	1 mL/min	0.39 minutes	51
4	Dutasteride	Human plasma	Xterra MS C18 column	10 mM ammonium formate and acetonitrile in a 15:85 (volume/volume) ratio	-	0.6 mL/min	1.2-minute	52

Table 5: Gas Chromatography-Mass Spectrometry method for analysis of Dutasteride

Sr. No.	Drug	Matrix/ Dosage Form	Stationary Phase	Carrier Gas	Retention time (min.)	Flow Rate	Ref. No.
1	Dutasteride	Tablet	DB-5MS column (phase composition: 5% phenyl-methylpolysiloxane ñ 95% phenyl arylene polymer)	Nitrogen	-	-	53

acetonitrile and water in a 60:40 (v/v) ratio. Dutasteride was detected using UV at 210 nm, with a retention time of approximately 10 minutes. The method demonstrated linearity over a concentration range of 0.2–1 μg/mL, with an R^2 value of 0.997.[47]

Noel A. Gomes et. al. developed a stability-indicating LC–MS method for analyzing dutasteride in human plasma. A Hypurity C18 column (50 x 4.6 mm i.d., 5 μm particle size) was used for the analysis. The mobile phase consisted of acetonitrile in a 20:80 (v/v) ratio, 10 mM ammonium formate buffer, and pH adjusted with formic acid to 3.00 ± 0.05. A constant flow rate of 0.6 mL/min was maintained.This method was validated for dutasteride concentrations ranging from 0.1 to 10.0 ng/mL and featured a rapid run time of 2.5 minutes, enabling the analysis of over 180 human plasma samples per day.[48]

Sangita Agarwal et. al. developed a stability-indicating LC–MS method for analyzing dutasteride in human plasma. Liquid-liquid extraction and chromatography on a Gemini C-18 column (50 mm x 2.0 mm, 3 μm) were the steps in the procedure. The ratio of methanol to ammonium formate in the mobile phase was 97:3 (v/v). a retention time of approximately 0.39 minutes.With a quick run time of just one minute per sample, the LC system operated isocratically at a flow rate of one milliliter per minute.The internal standard concentration in the plasma samples was 8.0 ng/mL.[49]

N.V.S. Ramakrishna et. al. described a method for evaluating the stability of dutasteride in pharmaceutical formulations using LC–MS with human plasmaThe procedure made use of a reverse phase Xterra MS C18 column with a mobile phase consisting of 10 mM ammonium formate and acetonitrile in a 15:85 (v/v) ratio. Formic acid was used to bring the pH down to 3.0. The assay demonstrated a linear dynamic range for dutasteride in human plasma, ranging from 0.1 to 25.0 ng/mL. With a rapid run time of 1.2 minutes per sample, the method enabled the analysis of more than 400 plasma samples daily, and a flow rate of 0.6 mL/min provided well-resolved peaks.[50]

7. Gas Chromatography-Mass Spectrometry

Aleksandra Groman et al. developed a direct standard headspace method using GC-MS to analyze benzene, carbon tetrachloride, and 1,2-dichloroethane in dutasteride drug substance. Nitrogen was used as the carrier gas at 60 kPa with a split ratio of 4:1 in a DB-5MS column containing 5% phenyl-methylpolysiloxane and 95% phenyl arylene polymer for the analysis. The gas chromatograph was injected with a 2 μL sample. Characteristic ions for detection were benzene at m/z 78, carbon tetrachloride at m/z 117, and 1,2-dichloroethane at m/z 62.[51]

8. Conclusion

Numerous methods can be employed to assess the presence of dutasteride in pharmaceutical formulations and biological materials. The study of the published data showed that the measurement of Dutasteride in different pharmaceutical dosage form, serum was frequently done using HPLC methods. Because this technology yields precise results and is less expensive than more sophisticated detection techniques, HPLC with UV detection is appropriate. This review provided a summary of the most cutting-edge analytical techniques available for identifying Dutasteride.

This review will be valuable to analytical chemists by providing insights into the essential solvents and their combinations for the analytical tools available in the laboratory. Utilizing the most effective set of parameters can reduce both the time and cost of analyses while ensuring reliable results. Additionally, these techniques will aid in selecting optimal parameters for in-process analysis during API production.

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None.

10. Conflict of Interest

None.

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