RESEARCH PAPER

Design, Development and ICH-Compliant Validation of a Stability-Indicating RP-HPLC Method for Finasteride Analysis

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ABSTRACT

A reliable and well-validated RP-HPLC analytical procedure was established for the quantitative determination of Finasteride and its formulation. Efficient separation was accomplished on a C18 column employing an optimized mobile phase composition consisting methanol and water with orthophosphoric acid (95:5 v/v); at a flow rate of 1.0 mL/min and detection at 210 nm. Finasteride was eluted at 4.5 min. The developed method underwent validation in accordance with established ICH regulatory guidelines. The developed method exhibited the excellent linearity (r^2 value was 0.9977) in the range of 10 - 35 ppm. The %RSD was found less than 2% indicates the precision of the method. The method's capability to indicate stability was demonstrated through comprehensive forced degradation studies. The developed method of Finasteride demonstrates its suitability for routine quality check of Finasteride in pharmaceutical preparations.

Keywords: Finasteride, Stability-Indicating method, Validation, RP-HPLC, ICH guidelines.

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INTRODUCTION

Finasteride represents a synthetic analog of the 4-azasteroid class, employed in the therapeutic management of benign prostatic hyperplasia as well as androgenetic alopecia[1]. (Figure 1) It acts by inhibiting type II 5α-reductase enzyme. Given its significant therapeutic value, there is a necessity for precise and dependable analytical methodologies for its quantification within pharmaceutical preparations[2].

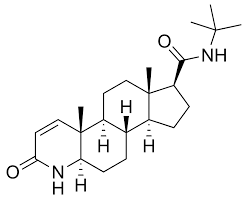

Figure 1. Finasteride Structure

Several analytical methods including RP-HPLC, LC-MS and spectrophotometry have been reported for Finasteride determination. However, there remains a need for simple, rapid and cost-effective validated methods suitable for the routine analysis of Finasteride. RP-HPLC methods are widely preferred due to their sensitivity, reproducibility and compliance with regulatory requirements[3].

The present study is based on development and validation a stability-indicating RP-HPLC method for Finasteride.

MATERIALS AND METHODS

Chemicals and Reagents

Finasteride working standard along with HPLC-grade methanol and purified water were employed for the analysis. The mobile phase was prepared using orthophosphoric acid (OPA).

Instrumentation

The analysis was performed using HPLC system (Jasco 4600) with a UV detector and ChromNAV software for data acquisition and processing.

Preparation of Solutions

A precisely weighed quantity of 10 mg of Finasteride was dissolved in the mobile phase, followed by sonication. The resulting solution was then filtered prior to analysis.

Mobile Phase Selection

Different solvent combinations were explored considering the physicochemical characteristics of the drug and an extensive review of the literature to achieve optimal separation and method optimization[4]. Among the evaluated conditions, methanol and water supplemented with orthophosphoric acid (OPA) was found to be most suitable mobile phase. The optimized mobile phase comprised solvent A as methanol (95%) and solvent B as water (5%) with OPA, providing appropriate polarity and pH conditions for efficient chromatographic separation.

Method Development

The RP-HPLC method development for the analysis of Finasteride was carried out systematically to achieve optimal separation, sensitivity and reproducibility. Various chromatographic parameters were carefully evaluated and optimized by considering the physicochemical characteristics of the drug along with insights from reported literature.

Different chromatographic parameters were systematically assessed and optimized at the initial stage, various stationary phases were evaluated and a C18 column was selected as it is compatible with non-polar to moderately polar compounds, resulting in improved retention behavior and symmetric peak shapes.

Various ratios of organic and aqueous components were systematically investigated to establish an optimized mobile phase composition. Methanol and water containing orthophosphoric acid (OPA) were selected as the mobile phase, as this combination provided sharp peaks, good resolution and acceptable retention time. The mobile phase was optimized to ensure enhanced chromatographic resolution and performance.

The detection wavelength was chosen in accordance with the UV absorption profile of Finasteride. Based on the UV absorption profile, 210 nm was selected as the detection wavelength, as it offered enhanced sensitivity for reliable detection and quantification.

Further refinement of the method was carried out using a systematic trial-and-error approach by modifying key parameters, like change in the flow rate, different compositions of the mobile phase as well as changing the temperature conditions of the selected column. These adjustments were aimed at achieving a well-resolved and symmetrical peak with minimal tailing along with an appropriate retention time. The optimized conditions demonstrated good robustness and reproducibility, indicating the suitability of the method for routine analytical applications.

Optimized Chromatographic Conditions

The optimized mobile phase consisted of methanol and water, supplemented with OPA (95:5 v/v), providing an acidic environment that improves peak shape and analyte ionization control. The analysis performed at a constant flow rate of 1.0 mL/min, ensuring optimal resolution and reasonable analysis time. Detection was carried out at 210 nm using a UV detector, a wavelength commonly selected for compounds with strong absorbance in the low UV region. Each chromatographic run was carried out with 20 µL injection volume and the temperature was maintained at 30°C to enhance reproducibility and stability of retention times. At the optimized conditions, the analyte was eluted at a retention time of around 4.5 minutes, indicating efficient and rapid separation suitable for routine analysis. (Figure 2)

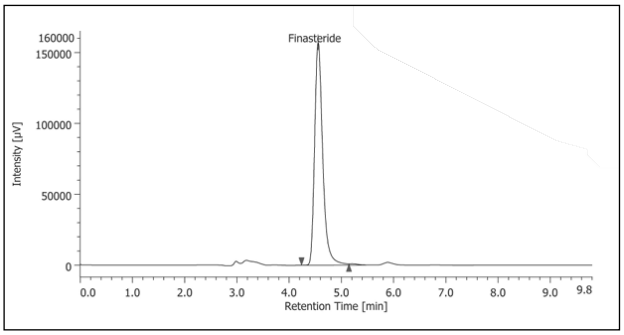

Figure 2. HPLC Chromatogram of Finasteride

Stress Studies

Stress testing was conducted to assess the stability characteristics of Finasteride to confirm stability-indicating performance of the method. Stress testing was conducted as per ICH guidelines (Q1A(R2) and Q1B), the Finasteride was exposed to different stress conditions to facilitate the degradation and to elucidate the underlying degradation pathways[5-7]. Such investigations are essential for demonstrating the specificity and reliability of analytical methods, particularly in distinguishing the analyte from its degradation products[8-10].

The Finasteride was exposed to a range of different stress conditions, like acidic, basic, photolytic, oxidative, thermal and aqueous degradation. The resulting degradation samples of each conditions were evaluated separately by the optimized method.

Acid-induced degradation study was conducted by subjecting the drug to hydrochloric acid solution (0.1 - 1 N HCl) under controlled thermal conditions for a predetermined time interval, followed by neutralization prior to analysis. (Figure 3)

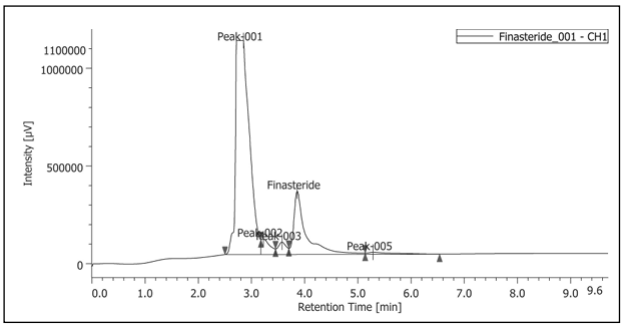

Figure 3. HPLC Chromatogram of Finasteride (Acidic degradation)

In alkaline degradation, the Finasteride was exposed to sodium hydroxide solution (0.1-1 N NaOH) under controlled temperature conditions, followed by neutralization with acid and subsequent HPLC analysis. (Figure 4).

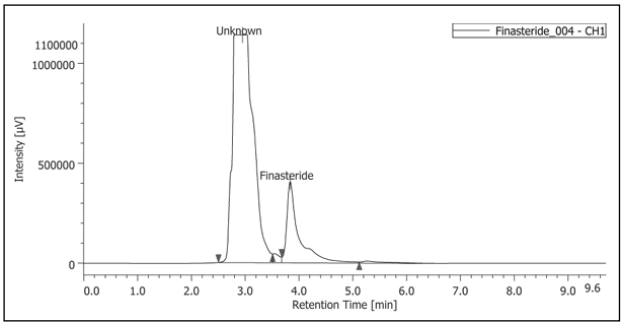

Figure 4. HPLC Chromatogram of Finasteride (Basic degradation)

Aqueous degradation studies were conducted by exposing the drug to water at room temperature or elevated temperature for a defined period to evaluate hydrolytic stability. (Figure 5)

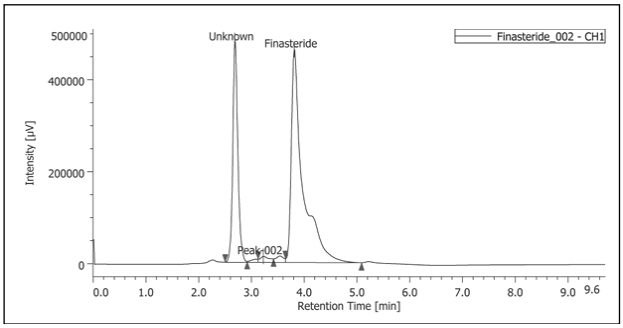

Figure 5. HPLC Chromatogram of Finasteride (Aqueous degradation)

Oxidative degradation was performed using hydrogen peroxide under controlled conditions to assess susceptibility to oxidative stress and identify possible oxidative degradation products. (Figure 6)

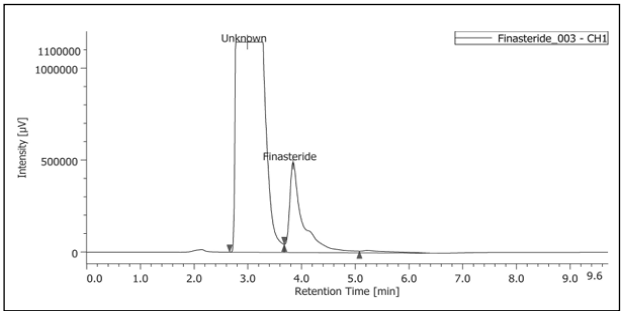

Figure 6. HPLC Chromatogram of Finasteride (Oxidative degradation)

Photodegradation was assessed by exposing the Finasteride to both ultraviolet and visible light conditions as per ICH Q1B guidelines to determine its photostability. (Figure 7)

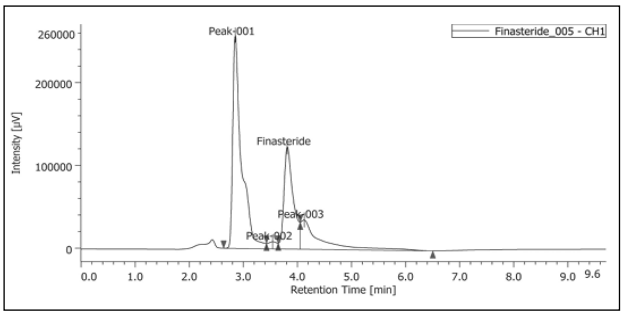

Figure 7. HPLC Chromatogram of Finasteride (Photolytic degradation)

Thermal stability studies were performed by exposing the drug substance to controlled high-temperature conditions (typically 40 - 80°C) under dry or humid conditions for a specified time to assess heat-induced degradation. (Figure 8)

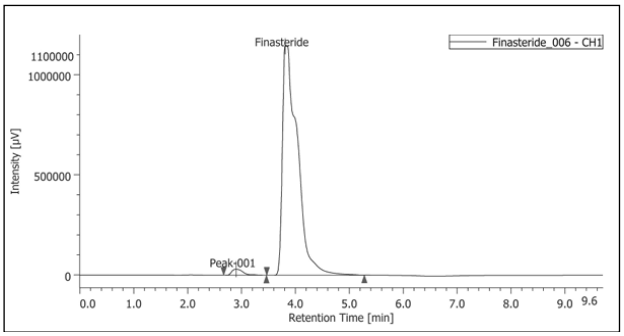

Figure 8. HPLC Chromatogram of Finasteride (Thermal degradation)

The stressed samples were analysed by developed RP-HPLC method to assess the extent of degradation as well as to monitor the formation of degradation products. The findings of the stress studies confirmed the stability-indicating in nature and the robustness of the developed method[11-14].

Method Validation

The developed method of Finasteride was validated in compliance with ICH Q2(R1) guidelines[15-18].

Specificity

Specificity of the method was determined by verifying the ability of the developed method to selectively separate and identify the Finasteride in presence of potential interfering substances, including impurities, degradation products and excipients. Blank, placebo, Standard and sample solutions were prepared and subsequently analyzed under optimized chromatographic conditions. Specificity was further confirmed by injecting blank and placebo without the analyte to examine any change in the retention time. No significant peaks were observed, confirming the absence of interference.

Linearity

It is done by evaluating a series of Finasteride standard solutions of different concentrations. The calibration curve was plotted as peak area versus concentration.

Precision

Precision studies of the developed method were conducted according to ICH guideline recommendations.

Accuracy:

Known amounts of Finasteride were added to pre-analyzed samples at three concentration levels (80%, 100% and 120%) and each level was analyzed in triplicate to ensure precision and reliability. The percentage recovery was calculated to assess method accuracy by analyzing spiked samples under optimized chromatographic conditions.

LOD

The detection limit (LOD) of the method was evaluated, as per the standard equation:

$LOD = (3.3 \times \sigma)/S$

LOQ

The quantification limit (LOQ) of the method was evaluated using the following relationship:

$LOQ = (10 \times \sigma)/S$

Robustness

Robustness was determined by change in optimized chromatographic conditions. The resulting effects on retention time, peak area and peak symmetry of Finasteride were analyzed.

System Suitability

System suitability parameters were evaluated before sample analysis to verify the system was appropriate for intended analytical application. These tests ensure the reliability, reproducibility and performance of the chromatographic system. A standard solution of Finasteride was injected under optimized chromatographic

conditions. To evaluate the different system suitability parameters.

RESULTS:

The developed RP-HPLC method demonstrated excellent performance characteristics. The retention time was short, enabling rapid analysis. Validation parameters met ICH acceptance criteria, indicating reliability. Compared with previously reported methods, the developed method is simpler, faster and uses a cost-effective mobile phase. The method also successfully separated degradation products, confirming its applicability for stability studies.

Method Development Results

The method for Finasteride was developed for optimal separation with good peak symmetry, resolution and acceptable retention time. Various chromatographic conditions were explored during method development. Among these, a C18 column was selected. Among tested mobile phases, methanol: water containing OPA (95:5 v/v) provided best performance. Addition of OPA improved peak symmetry and minimized tailing, likely by suppressing ionization.

Under optimized conditions, Finasteride showed sharp, well-resolved peak. Its retention time was found to be 4.5 minutes. Detection at 210 nm ensured adequate sensitivity based on its maximum absorbance.

No interference from blank or excipient components was observed, thereby confirming the specificity of the method. System suitability parameters were found to be within the acceptable limits, indicating satisfactory column efficiency and reproducibility.

Validation Results

Linearity

The developed method showed a strong linear response between 10 - 35 ppm. The calibration curve showed a linear relationship between concentration and peak area (r^2 = 0.9977), reflecting sensitivity and reliability of the method. The linear regression confirms that the method is suitable for quantitative analysis across the working range. (Figure 9).

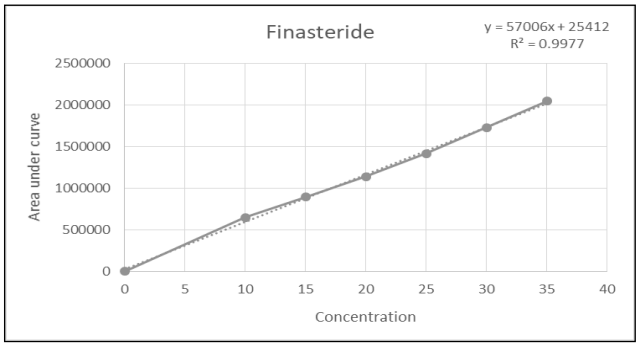

Figure 9. Linearity Graph of Finasteride

Precision

The %RSD of 1.858% was within the specified acceptance limit, demonstrating good precision. Method precision showed %RSD of 0.621%, confirming repeatability of the method.

Intermediate precision also demonstrated low variability, with %RSD of 0.836% and 0.154%, respectively. These findings showed that the method is highly precise under normal laboratory conditions. All values were within acceptable limits (<2%).

Accuracy

Recovery of Finasteride was calculated by comparing the amount obtained with the amount spiked. The average recovery values were fund to be 99.2 - 100.1% and the %RSD values were less than 2%, demonstrating the accuracy and reliability of the method. The obtained results validate the accuracy of the developed method (Table 1).

Table 1. Recovery Study of Finasteride

Level (%)	Amount Added (µg/mL)	Amount Found (µg/mL)	% Recovery	% RSD
80 %	8	7.94	99.2	1.21
100 %	10	10.01	100.1	0.98
120 %	12.0	11.95	99.6	1.05

Specificity

The chromatographic analysis confirmed that blank or excipients was not interfering in the retention time of Finasteride (4.5 min).

Robustness

The % RSD values were consistently below 2%, with no significant impact on system suitability parameters. (Table 2).

Table 2. Robustness of Finasteride

Robustness parameters	Peak Area	% RSD	Peak tailing	Theoretical plates
Wavelength (±2 nm)	2402411	1.247%	1.351	4716
	2457388		1.351	4681
	2408174		1.355	4680
	1941791	1.117%	1.345	4595
	1946237		1.341	4563
	1906849		1.359	4751
Flow rate (±0.2 mL/min	2381195	1.731%	1.499	5740
	2300611		1.458	5420
	2349143		1.502	5789
	1405235	0.736%	1.319	4135
	1417963		1.327	4018
	1425884		1.341	3931
Injection volume (±2 µL)	1823156	0.133%	1.395	4519
	1827083		1.328	4452
	1822624		1.393	4492
	1811736	0.017%	1.406	4543
	1811503		1.373	4526
	1811128		1.379	4592

LOD

The LOD value for Finasteride was 0.12 µg/mL. The obtained low LOD value reflects high sensitivity of the method for detecting trace amounts of Finasteride.

LOQ

The LOQ value for Finasteride was found to be 0.36 µg/mL. This implies method has adequate sensitivity for the precise and accurate quantification of Finasteride at low concentration levels. The % RSD at the LOQ level was found to be within acceptable limits (< 2%), confirming good precision. The validation outcomes are summarized in Table 3.

Table 3. Result of Validation

Parameter	Acceptance Criteria
Specificity	No interference was observed at the retention time of the analyte.
Linearity	$r^2 > 0.9977$
Accuracy	98 - 102% recovery %RSD < 2
Precision	% RSD < 2
LOD	0.12 µg/mL
LOQ	0.36 µg/mL
Robustness	within acceptable limits
System Suitability	Plate count > 2000 Tailing factor < 2 %RSD < 2.0

Stress Studies

Significant degradation was observed under photolytic conditions (83.39%), indicating high sensitivity of Finasteride to light exposure. Moderate degradation occurred under acidic (42.79%) and basic (29.51%) conditions, while oxidative stress showed minimal degradation (7.21%), suggesting relative stability in oxidative environments. Under thermal conditions, the chromatographic profile did not indicate significant degradation, as evidenced by the presence of a well-defined and dominant Finasteride peak with no substantial increase in degradation products. This suggests that Finasteride is relatively stable under thermal stress. These observations further confirm its stability-indicating nature (Table 4).

Table 4. Stress stability of Finasteride

Forced degradation type	Degraded peak AUC	% Degradation
Acidic degradation	5112836	42.79
Basic degradation	6299772	29.51
Aqueous degradation	7042049	21.20
Oxidative degradation	8292885	7.21
Photolytic degradation	1484640	83.39

DISCUSSION:

Earlier methods for Finasteride analysis include RP-HPLC, LC-MS and spectrophotometric techniques, many of which involve complex mobile phase compositions, longer retention times or require expensive instrumentation. Some reported HPLC methods also lack stability-indicating capability or require gradient elution, thereby limiting their suitability for routine quality control analysis.

In contrast, the present method offers several advantages. The use of methanol and water with orthophosphoric acid (OPA) in a high organic ratio (95:5 v/v) enables rapid elution with short retention time (4.5 minutes). This significantly reduces analysis time and solvent consumption, making the method cost-effective.

The method demonstrated excellent linearity, precision, and accuracy in accordance with ICH guidelines, along with adequate sensitivity as indicated by low LOD and LOQ values. Additionally, the method was proven to be stability-indicating through forced degradation studies, as it effectively separated Finasteride from its degradation products without interference.

Compared to previously reported methods, the developed method is simpler, faster and more economical while maintaining high analytical performance.

CONCLUSION:

An accurate, simple, precise and robust RP-HPLC method was successfully developed and validated for the estimation of Finasteride as per ICH guidelines. The developed stability-indicating method provided rapid and reliable quantification of Finasteride in pharmaceutical formulations. The optimized conditions yielded a well-resolved peak, demonstrating effective separation. The method exhibited excellent analytical performance, as demonstrated by good linearity, precision, accuracy and sensitivity. The low %RSD values and satisfactory recovery results confirmed the reproducibility and reliability of the method. Additionally, LOD and LOQ values indicated adequate sensitivity for detecting and quantifying Finasteride at low concentration levels. The method exhibited robustness and stability-indicating nature.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation.

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