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Method Development and Validation for The Simultaneous Estimation of Finasteride and Tamsulosin Hydrochloride by RP-HPLC

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ABSTRACT
A simple, rapid, accurate, precise, and economical RP-HPLC method was developed and validated for the simultaneous estimation of Finasteride (FINA) and Tamsulosin HCL (TAM) in pharmaceutical dosage forms. Chromatographic separation was achieved using a Shim-pack C8 column with HPLC acetonitrile: HPLC grade water (pH adjusted to 3.0, with 1% Ortho phosphoric acid) (70:30, % v/v) as the mobile phase at a flow rate of 1.0 mL/min and UV detection at 223 nm. The method showed good linearity over 10–50 µg/mL for both drugs, with R^2 of 0.9955 of FINA and 0.9917 of TAM. Accuracy was confirmed by recovery studies, with recoveries of 98.76-98.23% for FINA and 101.92-101.56% for TAM. Precision showed %RSD below 2%. The method was also validated for LOD, and LOQ according to ICH guidelines and was suitable for routine analysis.

KEYWORDS: Finasteride, Tamsulosin HCL, Simultaneous Estimation, RP-HPLC, Benign prostatic hyperplasia, ICH Guidelines.

I. INTRODUCTION:

Disease: Benign Prostatic Hyperplasia (BPH) is a non-cancerous enlargement of the prostate gland that commonly occurs in aging men. It can compress the urethra and cause lower urinary tract symptoms such as frequent urination, difficulty in urination, and weak urine flow. It affecting approximately one-third of men aged over 50 years. Combined therapy with alpha-adrenergic blockers and 5-alpha reductase inhibitors is considered an effective long-term treatment due to its enhanced patient acceptance and clinical efficacy. The combination has been reported to decrease prostate size by up to 26% while reducing the likelihood of BPH-related surgical intervention by approximately 57%.[1]

- **Finasteride (FIN)**, chemically known as **N-(1,1-dimethylethyl)-3-oxo-4-aza-5-androst-1-ene-17-carboxamide**, is a **type II 5-alpha reductase inhibitor** thatgradually decreases prostate volume. The growth and normal function of the prostate are regulated by **dihydrotestosterone (DHT)**, which is produced from testosterone by the action of the **5-alpha reductase enzyme**. By inhibiting this enzyme, finasteride lowers DHT levels, leading to a reduction in prostate size.[2]

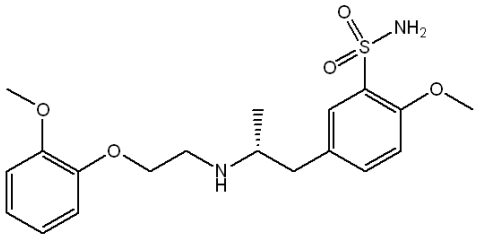

Figure No1: Finasteride: (1S,3aS,3bS,5aR,9aR,9bS,11aS)-N-tert-butyl-9a,11a-dimethyl-7-oxo-1,2,3,3a,3b,4,5,5a,6,9b,10,11-dodeachydroindeno[5,4f] quinolone-1-carboxamide.[3]

- **Tamsulosin (TAM)**, chemically named **5-[(2R)-2-[[2-(2-ethoxyphenoxy) ethyl] amino] propyl]-2-methoxybenzenesulfonamide**, is a **selective alpha-1 adrenergic receptor blocker**. Alpha-1 receptors are highly concentrated in the prostate, prostatic capsule, prostatic urethra, and bladder neck, where they regulate smooth

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muscle contraction through sympathetic stimulation. Blocking these receptors relaxes the smooth muscles of the prostate and bladder neck, improving urinary flow and relieving the symptoms associated with **benign prostatic hyperplasia (BPH).**[4]

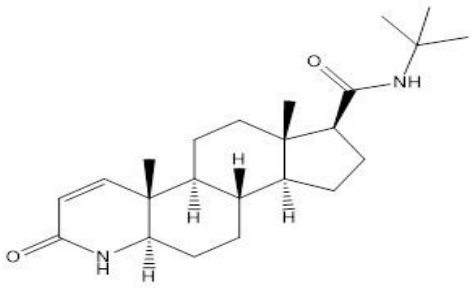

Figure No 2: Tamsulosin Hcl: 5-[(2R)-2[2-(2-ethoxyphenoxy) ethylaminopropyl]-2-methoxybenzene Sulphonamide.[5]

II. MATERIALS AND METHODOLOGY

2.1 Materials:

Finasteride and Tamsulosin HCL active pharmaceutical ingredients (APIs) were received as gift samples from CTX Life Sciences Pvt. Ltd., Surat, Gujarat, India. The marketed formulationsUrimax were procured from a local pharmacy in Bangalore, India, and used for the present study. HPLC-grade methanol and acetonitrile, procured from Avantor Performance Materials India Pvt. Ltd., Thane, Maharashtra, India, were used as solvents throughout the study. Double-distilled water was used for all analytical procedures.

Chromatographic analysis was performed using a Shimadzu Liquid Chromatograph (LC-20AT) equipped with a binary pump, UV–Visible detector (Shimadzu SPD-20A), Rheodyne injector (Model 7725i, 20 µL loops), and LabSolutions software (Version 5.90). Separation was carried out using a Shimadzu Shim-pack C8 column (4.6 × 250 mm, 5 µm). A Hamilton syringe (25 µL) was used for sample injection. The mobile phase and sample solutions were filtered through Nylon membrane filters (25 mm, 0.2 µm) and degassed using an ultrasonic cleaner (RC Systems MU1700). A Shimadzu UV-1700 UV–Visible spectrophotometer with UV Probe software (Version 2.32) was used for absorbance measurements, while a Value High Reliability Vacuum Pump was used for filtration. All glassware used was made of borosilicate glass and calibrated before use. Chemicals were weighed using a calibrated Sartorius TE-214S digital analytical balance (maximum capacity 200 g).

2.2 Methodology:

2.2.1 Selection of Analytical Wavelength:

To determine the appropriate analytical wavelength for the simultaneous estimation of FINAand TAM, standard solutions of FINA (20 µg/mL) and TAM (20 µg/mL) were prepared using HPLC-grade water. The solutions were scanned individually over the UV range of 200–400 nm, and the overlaid spectra were evaluated to select the analytical wavelength. The overlay spectra are shown in Figure 3.

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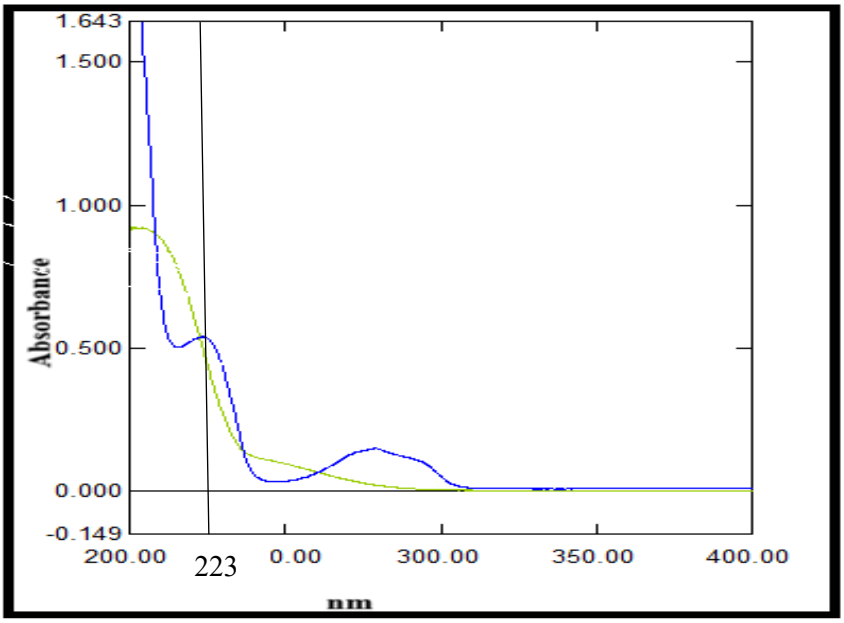

Figure No 3: Overlay spectra of FINA (20µg/mL) and TAM (20µg/mL)

2.4.2. Finalized Chromatographic Conditions

✓ **Analytical Column:** Shim pack C8(4.6× 200 mm, 5 µm)
✓ **Mobile Phase:** ACN:Water Ph 3.0, adjusted with 1% Ortho phosphoric acid(70:30 % v/v)
✓ **Injection volume:** 20 µl
✓ **Flow rate:** 1 ml/min
✓ **Detection Wavelength:** 223 nm
✓ **AUFS:** 0.1000
✓ **Pressure** ~ 12.6 MPa

2.3.3 Preparation of Mobile Phase

The mobile phase was prepared by mixing 700 mL of HPLC-grade acetonitrile with 300 mL of HPLC grade wate. (pH adjusted to 3.0, with1% Ortho phosphoric acid) (70:30, % v/v). The prepared mobile phase was filtered through a 0.2 µm membrane filter under vacuum and sonicated for 10 minutes before use.

2.4.4. Preparation of Standard Stock Solution

I. Preparation of Standard Solution of Finasteride:

An accurately weighed quantity of 10 mg of Finasteride was transferred into a 10 ml volumetric flask and dissolved in HPLC-grade methanol. The volume was made up to the mark with the same solvent to obtain a standard stock solution containing 1000 µg/ml, labelled as Std Stock FINA (A). Subsequently, 1 ml of this stock solution was transferred into a 10 ml volumetric flask and diluted upto the mark with HPLC-grade water to obtain a working standard solution of 100 µg/ml, designated as Std Stock FINA (B).

II. Preparation of Standard Solution of Tamsulosin HCL:

An accurately weighed quantity of 10 mg of Tamsulosin HCL was transferred into a 10 ml volumetric flask and dissolved in HPLC-grade methanol. The volume was then made up to the mark with the same solvent to obtain a standard stock solution containing 1000 µg/ml, labelled as Std Stock TAM (A). Thereafter, 1 ml of this stock solution was pipetted into a 10 ml volumetric flask and diluted upto the mark with HPLC-grade water to obtain a working standard solution of 100 µg/ml, designated as Std Stock TAM (B).

2.4.5. Preparation of Calibration Curve for FINA and TAM

Aliquots of 1.0, 2.0, 3.0, 4.0 and 5.0 ml ofStd Stock FINA (B) were pipetted out into five separate 10 ml volumetric flasks. Similarly, 1.0, 2.0, 3.0, 4.0 and 5.0 ml ofStd Stock TAM (B)were pipetted out into the same respective volumetric flasks. The flasks were labelled as C1, C2, C3, C4, and C5 and the volume was made up to the mark with HPLC-grade water to obtain final concentrations of 10-50 µg/ml for FINA and 10–50 µg/ml for TAM.

The prepared solutions were filtered through a 25 mm, 0.25 µm nylon syringe filter and 20 µl of each solution was injected into the Rheodyne injector of

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the HPLC system. Chromatograms were recorded under the optimized chromatographic conditions after achieving a stable baseline. The peak areas of both drugs were measured for each concentration.
The overlay chromatograms of the calibration solutions are presented in Figure No. 4. Calibration curves for FINA and TAM were constructed by plotting peak area versus concentration, as shown in Figure No. 5 and Figure No 6. The results of the calibration study are summarized in Table No. 1 and Table No. 2.

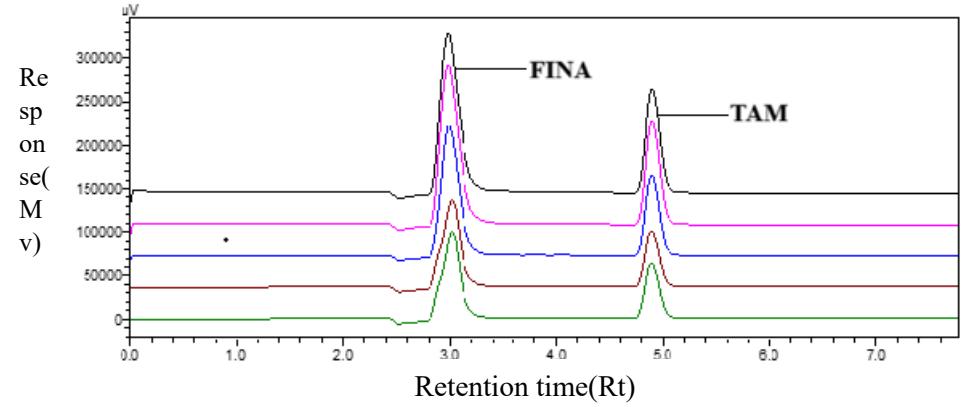

Figure No: 4. Overlain Chromatograms of FINA (10-50 µg/ml) and TAM (10-50 µg/ml).

2.4.6 Analysis of tablet formulation:

Twenty Capsules (Urimax F, Finasteride 5mg and Tamsulosin HCL 0.4 mg) were weighed and crushed to obtain fine powder. An accurately weighed tablet powder equivalent to 5mg of Finasteride and 0.4 mg of Tamsulosin HCL was transferred to 10 ml volumetric flask and 5ml of HPLC-grade methanol was added then sonicated for 10 min. The volume was made up to the mark with the same solvent and sonicated for 10 min containing 500 µg/ml and 40 µg/ml. The resulting solution was filtered through Whatman filter paper No. 41 and designated as 'Sample Stock A'. From the above 'Sample Stock A' solution, 2 ml of the aliquot was pipetted out and transferred to a 10 ml volumetric flask and it is labelled as 'Sample Stock B'(100 µg/ml of FINA, 8 µg/ml of TAM). From the 'Sample Stock B' 2 ml of aliquot is pipetted out and transferred to 10 ml of volumetric flask and make with HPLC grade water containing (20 µg/ml of FINA and 1.6 µg/ml of TAM) SamplesolutionwasfilteredthroughNylon25mm,0.2µmfilter using syringe and followed by injection into the Rheodyne injector (20 µl) of HPLC systemusingtheHamiltonSyringe.Samplechromatogramswere recorded under the finalized chromatographic conditions as described above after getting a stable baseline. Peak areas were recorded for all the peaks.The assay isdetermined by using single point calibration method. The assay results are presented in Table No. 4, and the corresponding chromatograms are shown in Figure No. 5.

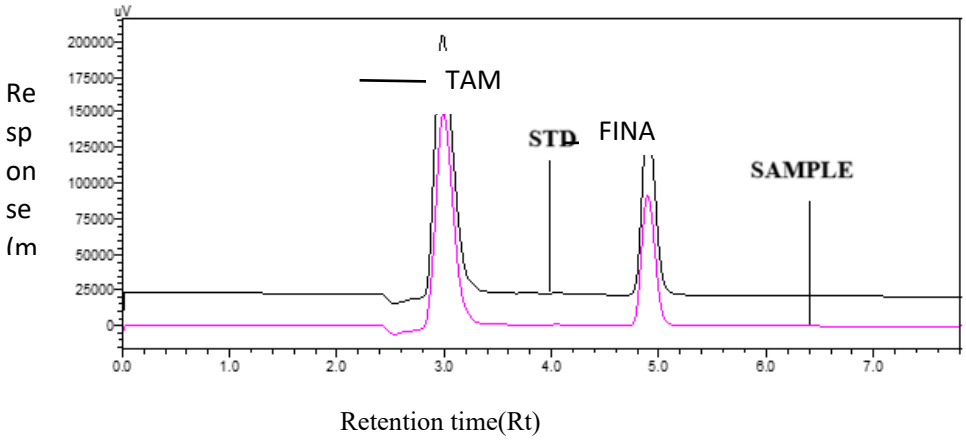

Figure No: 5 Overlay Chromatograms of Sample and Standard Solution of FINA and TAM at 223 nm.

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2.5 Validation of RP-HPLC Method.

2.5.1 **Linearity and Range**

The linearity of the method was evaluated by preparing and analysing FINA standard solutions in the concentration range of 10-50µg/mL andTAM standard solutions in the concentration range of 10–50 µg/mL The linearity of the method was established based on the correlation coefficient (R^2) obtained from the calibration curves

2.5.2 Precision

The precision of the developed analytical method was evaluated by assessing repeatability and intermediate precision.

2**.5.3 Accuracy**

The accuracy of the developed method was evaluated using the recovery study. Twenty tablets were accurately weighed, powdered, and used for analysis. Recovery studies were performed by spiking the pre-analysed sample with known concentrations of standard FINA (4, 5, and 6 µg/mL) and standard TAM (0.32, 0.40, and 0.48µg/mL) at three concentration levels, namely 80%, 100%, and 120%. The percentage recovery was calculated for each level, and the results are presented in Table No. 5.

2.5.4 Repeatability

Repeatability of the developed method was evaluated by preparing standard solutions of FINA (10 µg/mL) and TAM (20 µg/mL) and analysing each solution six times under identical experimental conditions. The standard deviation (SD) and percentage relative standard deviation (%RSD) were calculated to assess the repeatability of the method. The results are presented in Table No. 7.

2.5.5 Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The limit of detection (LOD) and limit of quantitation (LOQ) were determined using the standard deviation of the y-intercepts of six calibration curves and the average slope of the corresponding calibration curves. The values were calculated using the following equations:

$$\text{LOD} = 3.3 \times \frac{\text{Standard Deviation of y-Intercepts of Six Calibration curves}}{\text{Average Slope of Six Calibration Curves}}$$

$$\text{LOQ} = 10 \times \frac{\textit{Standard Deviation of y-Intercepts of Six Calibration curves}}{\textit{Average Slope of Six Calibration Curves}}$$

The calculated LOD and LOQ values are presented in Table No. 3**.**

III. RESULT:

Table No: 1. Results of Calibration Curve of FINA at 223 nm

Conc (µg/mL)	Peak area	SD	%RSD
10	413417.5	2096.339	0.507075
20	1449790	16778.55	1.157309
30	2151304	25994.55	1.208316
40	3144898	30337.6	0.964661
50	3950092	19914.27	0.504147

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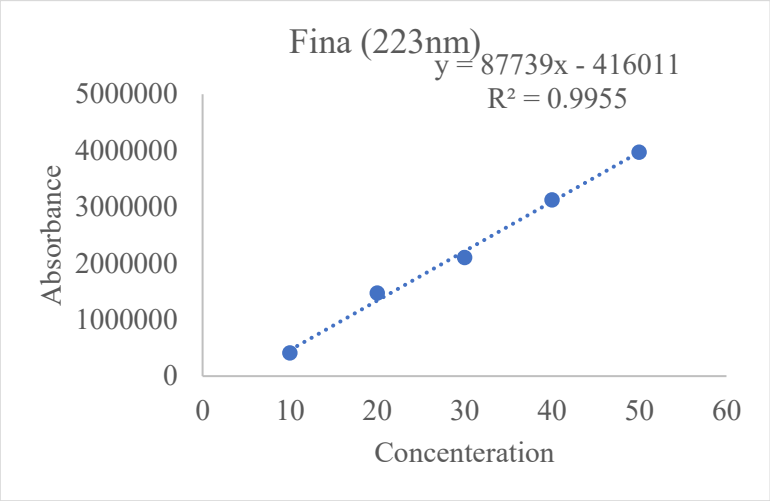

Figure No: 6. Calibration Curve of FINA at 223 nm.

Table No: 2. Results of Calibration Curve of TAM at 223 nm.

Conc (µg/mL)	Peak area	SD	%RSD
10	628585	658.4363	0.104749
20	1608453	4557.205	0.283329
30	2064991	3731.532	0.180705
40	2932738	3633.711	0.123902
50	3659197	3851.686	0.10526

Figure No: 7. Calibration Curve of TAM at 223 nm.

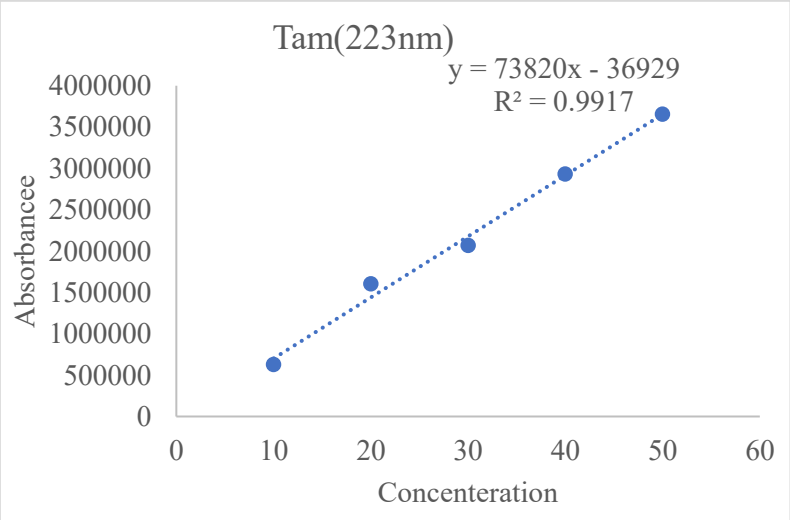

Table No: 3. Linear Regression Analysis of FINA and TAM at 223 nm.

Parameters	FINA	TAM
Beer's law limit (µg/ml)	10 to 50	10 to 50

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Wavelength (nm)	223	223
(Correlation Coefficient) R^2	0.9955	0.9917
Slope	87739	73820
Intercept	416011	36929
LOD (µg/ml)	0.038529	0.011193
LOQ (µg/ml)	0.116753	0.033919

Table No: 4. Assay Results

Amount Present(µg/ml)		**Amount Found(µg/ml)**		**%ASSAY**	
FINA	**TAM**	**FINA**	**TAM**	**FINA**	**TAM**
5	0.4	5.099	0.396	101.98	99.11
5	0.4	5.087	0.394	101.74	98.73
5	0.4	5.104	0.395	102.08	98.78
5	0.4	5.141	0.392	102.82	98.002
5	0.4	5.145	0.393	102.9	98.375
5	0.4	5.131	0.395	102.63	98.88
MEAN		5.117833	0.394167	102.3583	98.64617
SD		0.024269	0.001472	0.486474	0.395788
%RSD		0.474197	0.373436	0.475265	0.40122

Table: 5 Results of Accuracy

Levelof % Recovery	**Sr. No.**	**Amount of Standard DrugAdded (µg/ml)**		**TotalAmount Found(µg/ml)**		**TotalAmount Recovered (µg/ml)**		**%Recovery**	
		FINA	**TAM**	**FINA**	**TAM**	**FINA**	**TAM**	**FINA**	**TAM**
80 %	**1**	4	0.32	9.0455	0.7191	4.045	0.3191	101.13	99.74
	2	4	0.32	9.1007	0.7215	4.100	0.3251	102.51	100.49
	3	4	0.32	9.0848	0.7169	4.084	0.3169	102.12	99.04
100 %	**1**	5	0.4	9.998	0.7995	4.998	0.3995	99.96	99.88
	2	5	0.4	10.035	0.7992	5.035	0.3992	100.70	99.82
	3	5	0.4	10.042	0.8030	5.042	0.4030	100.84	100.75
120%	**1**	6	0.48	11.086	0.8715	6.086	0.4715	101.43	98.23
	2	6	0.48	11.098	0.8719	6.098	0.4719	101.63	98.31
	3	6	0.48	11.098	0.8711	6.098	0.4711	101.63	98.16

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Table:6. Statistical Validation Data for Accuracy Study

Level of % Recovery	Mean* (% Recovery)		±SD		%RSD	
	FINA	TAM	FINA	TAM	FINA	TAM
80%	101.92	99.76	0.710	0.024	0.696	0.724
100%	100.50	100.15	0.472	0.014	0.470	0.525
120%	101.56	98.23	0.116	0.019	0.114	0.080

Table No: 7. Results of Repeatability Study for FINA and TAM

SL. No.	Peak Area	
	FINA (10 µg/ml)	TAM (20 µg/ml)
1	628658	1405917
2	623675	1402567
3	624567	1415672
4	629878	1405687
5	629867	1404563
6	623489	1404785
Mean	626689	1406532
±SD	3097.53	4632.106
% RSD	0.494269	0.329328

IV. CONCLUSION

A simple, accurate, precise, reproducible, and cost-effective RP-HPLC method was successfully developed and validated for the simultaneous estimation of Finasteride and in pharmaceutical dosage forms. The method was validated in accordance with ICH guidelines and demonstrated satisfactory results for parameters including linearity, assay, accuracy, precision, limit of detection, and limit of quantitation. Owing to its reliability and reproducibility, the developed method can be effectively employed for routine quality control analysis of these drugs in pharmaceutical formulations.

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