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METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE BY RP-HPLC METHOD IN PHARMACEUTICAL DOSAGE FORM

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Abstract:
Background: *A simple, rapid, precise, sensitive, and reproducible analytical method was developed for the quantitative estimation of Tamsulosin Hydrochloride and Dutasteride in pharmaceutical dosage forms using Reverse Phase High Performance Liquid Chromatography (RP-HPLC).*
Method: *Chromatographic separation of Tamsulosin HCl and Dutasteride was achieved using a Waters Alliance e2695 HPLC system equipped with a Luna Phenyl Hexyl column (250 × 4.6 mm, 5 µm). The mobile phase consisted of Acetonitrile and 0.1% TEA (pH 2.5 adjusted with OPA) in the ratio of 20:80 % v/v. The flow rate was maintained at 1.0 mL/min, and detection was performed at 257 nm using a photodiode array (PDA) detector under ambient temperature conditions.*
Results: *The chromatographic method showed good separation with acceptable system suitability parameters. The number of theoretical plates for both drugs was not less than 2000, and the tailing factor was less than 2, indicating efficient column performance. The percentage relative standard deviation (%RSD) of peak areas was found to be less than 2.0%, demonstrating good precision and repeatability of the method.Validation: The developed method was validated according to the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The validation parameters such as accuracy, precision, specificity, linearity, and robustness confirmed that the method is reliable and suitable for quantitative analysis.*
Conclusion: *The developed RP-HPLC method was found to be simple, economical, accurate, precise, and robust. Therefore, the method can be effectively used for routine quantitative analysis and stability studies of Tamsulosin Hydrochloride and Dutasteride in pharmaceutical dosage forms.*
Keywords: *RP-HPLC, Tamsulosin HCl, Dutasteride, Method validation, Stability indicating method.*

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INTRODUCTION:

Benign prostatic hyperplasia (BPH) is one of the most common urological disorders affecting ageing men worldwide. It is characterised by the non-malignant enlargement of the prostate gland, which can lead to obstruction of the urinary tract and a variety of lower urinary tract symptoms (LUTS) such as increased urinary frequency, urgency, nocturia, weak urinary stream, and incomplete bladder emptying. The prevalence of BPH increases significantly with age, affecting approximately 50% of men over the age of 50 and up to 80–90% of men over the age of 80. Due to its high prevalence and impact on quality of life, effective pharmacological Management of BPH is an important aspect of modern healthcare.

Among the therapeutic options available for the management of BPH, combination drug therapy has gained considerable importance. Two widely used drugs in this combination therapy are **dutasteride** and **tamsulosin hydrochloride**. Dutasteride belongs to the class of 5-alpha reductase inhibitors, while tamsulosin hydrochloride is an alpha-1 adrenergic receptor blocker. The combination of these two drugs provides a dual mechanism of action that helps relieve symptoms and slow the progression of the disease. Dutasteride works by inhibiting the conversion of testosterone to dihydrotestosterone (DHT), a hormone responsible for prostate enlargement. By reducing DHT levels, dutasteride helps decrease prostate volume and prevent further growth of the gland. On the other hand, tamsulosin hydrochloride acts by selectively blocking alpha-1 adrenergic receptors in the smooth muscles of the prostate and bladder neck, resulting in relaxation of these muscles and improvement in urinary flow.

Due to their complementary mechanisms, dutasteride and tamsulosin hydrochloride are often formulated together in pharmaceutical dosage forms for the treatment of BPH. Combination therapy has been shown to provide better symptomatic relief and improved clinical outcomes compared to monotherapy. As a result, pharmaceutical industries have developed combined dosage forms containing both active pharmaceutical ingredients (APIs). However, ensuring the quality, safety, and efficacy of such formulations requires accurate analytical methods for the simultaneous estimation of both drugs.

Analytical method development plays a critical role in pharmaceutical analysis. It involves designing a reliable procedure for the identification, separation, and quantification of pharmaceutical compounds in bulk drugs and dosage forms. The developed analytical method must be precise, accurate, reproducible, and capable of distinguishing the analyte from impurities, degradation products, and excipients present in the formulation. Among various analytical techniques, High Performance Liquid Chromatography (HPLC) has emerged as one of the most powerful and widely used methods in pharmaceutical analysis due to its high sensitivity, specificity, and versatility.

Reverse Phase High Performance Liquid Chromatography (RP-HPLC) is particularly popular for the analysis of pharmaceutical compounds because it allows effective separation of non-polar to moderately polar compounds. In RP-HPLC, a non-polar stationary phase such as C18 is commonly used, while the mobile phase typically consists of polar solvents like water, methanol, or acetonitrile. The interaction between the analyte molecules and the stationary phase determines their retention time and separation efficiency. RP-HPLC offers several advantages including excellent resolution, short analysis time, high reproducibility, and suitability for routine quality control analysis.

For combination drug products such as dutasteride and tamsulosin hydrochloride, the development of a simultaneous estimation method is particularly important. Simultaneous estimation refers to the determination of two or more drugs in a single analytical run. This approach reduces analysis time, solvent consumption, and operational costs while increasing laboratory efficiency. However, the simultaneous determination of multiple drugs presents several analytical challenges. These include differences in chemical properties, solubility, absorption characteristics, and retention behavior of the analytes. Therefore, careful optimization of chromatographic conditions such as mobile phase composition, flow rate, detection wavelength, column type, and temperature is necessary to achieve proper separation and accurate quantification.

In addition to method development, method validation is an essential step to ensure that the analytical method is suitable for its intended purpose. Method validation involves a series of experimental procedures used to demonstrate that the analytical method consistently produces reliable results. In pharmaceutical analysis, method validation is performed according to internationally recognized guidelines. The validation parameters typically include accuracy, precision, specificity, linearity, limit of detection (LOD), limit of quantification (LOQ), robustness, and system suitability. These parameters help confirm that the method is capable of producing consistent and reproducible results under different conditions.

Accuracy refers to the closeness of agreement between the measured value and the true value,

while precision indicates the degree of repeatability of the method under the same conditions. Linearity evaluates the ability of the method to produce results that are directly proportional to the concentration of the analyte within a given range. The limits of detection and quantification determine the smallest amount of analyte that can be detected or quantified with acceptable accuracy and precision. Robustness examines the reliability of the method under small variations in experimental conditions, such as changes in pH, flow rate, or mobile phase composition. System suitability tests are performed to verify that the chromatographic system is functioning properly before analysis.

The development and validation of a reliable RP-HPLC method for the simultaneous estimation of dutasteride and tamsulosin hydrochloride are therefore essential for pharmaceutical quality control. Such methods are required during various stages of drug development, manufacturing, and regulatory approval. They are also important for routine analysis of finished dosage forms to ensure that the drug content meets the specified standards. Accurate quantification of both drugs ensures that patients receive the correct dosage and helps maintain the therapeutic effectiveness of the formulation.

Furthermore, the increasing demand for combination drug products in the pharmaceutical market has highlighted the need for simple, rapid, and cost-effective analytical techniques. An optimized RP-HPLC method that allows simultaneous estimation of dutasteride and tamsulosin hydrochloride can significantly improve the efficiency of quality control laboratories. It also supports regulatory compliance by providing validated data on the quality and stability of pharmaceutical formulations.

Therefore, the present analytical study focuses on the development and validation of a Reverse Phase High Performance Liquid Chromatographic method for the simultaneous estimation of dutasteride and tamsulosin hydrochloride in pharmaceutical dosage forms. The method aims to achieve effective separation of both drugs with good resolution, acceptable retention time, and high sensitivity. In addition, the developed method is validated according to standard validation parameters to confirm its reliability and suitability for routine pharmaceutical analysis.

This study contributes to the field of pharmaceutical analytical chemistry by providing a systematic approach for the simultaneous determination of these two drugs in combined dosage forms. The validated RP-HPLC method can be effectively applied in quality control laboratories for the routine analysis of dutasteride and tamsulosin hydrochloride formulations, ensuring the safety, quality, and

2. AIM AND OBJECTIVES

2.1 Aim

The present study aims to develop and validate a stability-indicating **Reverse-Phase High-Performance Liquid Chromatography (RP-HPLC)** method for the simultaneous determination of **Tamsulosin Hydrochloride** and **Dutasteride** in bulk drug and pharmaceutical dosage forms.

2.2 Specific Objectives

The specific objectives of the present study are:

- To develop a simple, rapid, precise, and accurate RP-HPLC method for the simultaneous estimation of Tamsulosin Hydrochloride and Dutasteride in bulk drugs and pharmaceutical dosage forms.
- To validate the developed analytical method according to the guidelines of the **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)**. The validation parameters include system suitability, accuracy, precision, specificity, linearity, robustness, limit of detection (LOD), and limit of quantification (LOQ).
- To evaluate the stability-indicating capability of the developed method by performing forced degradation studies under different stress conditions such as acidic, alkaline, oxidative (peroxide), reductive, thermal, hydrolytic, and photolytic degradation.

2.3 Plan of Work

The present work is designed to develop and validate a reliable RP-HPLC method for the simultaneous estimation of Tamsulosin Hydrochloride and Dutasteride in bulk drugs and pharmaceutical dosage forms. The developed method will be optimized to achieve good resolution, sensitivity, and reproducibility. Furthermore, the method will be validated as per ICH guidelines to ensure its suitability for routine quality control analysis.

2.4 Experimental Plan for HPLC Method Development

The plan of work for the development and validation of the RP-HPLC method includes the following steps:

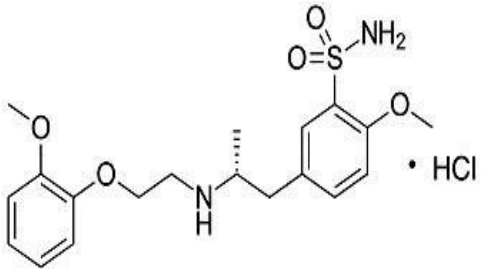
1. Collection of physicochemical and pharmacological information of the selected drugs.
2. Selection of appropriate chromatographic conditions, including:
   - Selection of the stationary phase (column)

- Selection of the mobile phase composition
- Optimisation of the flow rate

3. Selection of preliminary chromatographic separation conditions.
4. Optimisation of chromatographic and spectral parameters to achieve proper resolution of the analytes.
5. Validation of the developed analytical method according to ICH guidelines.
6. Application of the validated method for the analysis of commercial pharmaceutical dosage forms.
7. Finalisation of the analytical protocol and documentation of the results.

3. DRUG PROFILE

3.1.1 DRUG PROFILE OF TAMSULOSIN HCl



IUPAC name	5-[(2*R*)-2-[2-(2-ethoxyphenoxy) ethylamino] propyl]-2methoxybenzenesulfonamide; hydrochloride
Molecular Formula	C20H29ClN2O5S
Molecular Weight	445.0g/mol
Description	When men have symptoms of benign prostatic hyperplasia (BPH), an enlarged prostate gland, tamsulosin is used to help alleviate these symptoms. As men age, they may have benign enlargement of the prostate.
Therapeutic Category	Alpha blockers.

3.1.2 Uses:

When men have symptoms of benign prostatic hyperplasia (BPH), an enlarged prostate gland, tamsulosin is used to help alleviate these symptoms. As men age, they may have benign enlargement of the prostate.

3.1.3 Mechanism of action: Two types of adrenoceptors are blocked by tamsulosin: alpha-1A and alpha-1D. The alpha-1A subtype accounts for about 70% of the prostate's alpha-1 adrenoceptors. Blocking these adrenoceptors relaxes the prostate's smooth muscle and improves urine flow. Storage symptoms are prevented by relaxing the detrusor muscles of the bladder via inhibiting alpha-1D adrenoceptors.1 Because of its localisation specificity, tamsulosin is able to effectively treat the affected region while reducing its impact on other tissues.

3.1.4 Absorption:

Patients taking oral tamsulosin while fasting absorb 90% of the drug. For an oral dosage of 0.4 mg, the area under the curve is 151-199 ng/mL*hr, and for an oral dose of 0.8 mg, it is 440-557 ng/mL*hr. When taken orally, a 0.4 mg dosage achieves a maximum plasma concentration of 3.1–5.3 ng/mL, whereas a 0.8 mg dose achieves 2.5–3.6 ng/mL. The time it takes for tamsulosin to reach its peak concentration rises from four to six hours when taken with meals, while the drug is 30 percent more bioavailable and 40 to 70 percent more concentrated in the blood when taken without food.

3.1.5 Side effects:

- Sleepiness
- Weakness
- Back pain
- Diarrhea
- Runny nose

3.2 DRUG PROFILE OF DUTASTERIDE

Fig No. 13: Molecular structure of Dutasteride Table No. 6: **Drug profile of Dutasteride**

IUPAC name	(1*S*,3*aS*,3*bS*,5*aR*,9*aR*,9*bS*,11*aS*)-*N*-[2,5bis(trifluoromethyl)phenyl]-9*a*,11*a*-dimethyl-7-oxo1,2,3,3*a*,3*b*,4,5,5*a*,6,9*b*,10,11-dodecahydroindeno[5,4f]quinoline-1-carboxamide
Molecular Formula	C27H30F6N2O2
Molecular Weight	528.5 g/mol
Description	Acute urine retention, or the abrupt inability to pee, is less likely to occur while using dutasteride to treat benign prostatic hyperplasia (BPH). Another potential benefit of dutasteride is a reduced need for prostate surgery. The 5-alpha reductase inhibitor class includes dutasteride.
Therapeutic Category	5-alpha reductase inhibitors.

3.2.1 Mechanism of Action:

The 5α-reductase, an intracellular steroid enzyme mostly found in prostatic stromal cells and attached to the nuclear membrane, transforms testosterone into 5αdihydrotestosterone (DHT), an active metabolite. Most researchers believe that dihydrotestosterone (DHT) is the principal androgen involved in prostate growth and subsequent hypertrophy. Upon buildup inside the prostate gland, it acts as the hormonal mediator for hyperplasia. By acting on the androgen receptors, DHT regulates genes that are involved for cell proliferation. It's worth noting that DHT has a stronger affinity for androgen receptors in the prostate gland than testosterone. Type I 5α-reductase is found mostly in the sebaceous glands of the liver, most parts of the skin (including the scalp), and is responsible for producing about onethird of the DHT in circulation. The type II 5a-reductase isozyme, which accounts for over twothirds of the DHT in circulation, is mostly located in the liver, seminal vesicles, hair follicles, and the prostate. The reason dutasteride suppresses DHT so well is because it inhibits both isoenzymes of 5α-reductase. Dutasteride produces a near-complete suppression of blood DHT levels—more than 90%—in contrast to [finasteride], which reduces serum DHT levels by 70%.

Inhibiting the enzyme activity of type II and type II 5α-reductase, dutasteride prevents testosterone from being converted to 5α-dihydrotestosterone (DHT), the principal androgen responsible for the initial formation and subsequent growth of the prostate gland. Reducing serum DHT levels results in reduced prostatic volume and increased epithelial apoptosis. This is because it is proposed that DHT is the principal androgen responsible for prostatic growth in later life, normal masculinisation of the external genitalia, and the maturation of the prostate gland during development. When tested in both laboratory and living organism settings, dutasteride was shown to have a very slow rate of drug dissociation from the drug-enzyme complex, indicating that it is a selective and competitive inhibitor of Type I and Type II 5αreductase isoenzymes. The androgen receptor in humans is unbindable to dutasteride.

3.2.2 Uses: Acute urine retention, or the abrupt inability to pee, is less likely to occur while

using dutasteride to treat benign prostatic hyperplasia (BPH). Another potential benefit of dutasteride is a reduced need for prostate surgery. The 5-alpha reductase inhibitor class includes dutasteride.

3.2.3 Absorption: The peak serum concentrations were achieved within 2 to 3 hours after a single oral dosage of 0.5 mg dutasteride. Six months after starting treatment with 0.5 mg of dutasteride orally once daily, the target steady-state concentration of 40 ng/mL should be reached. Absolute bioavailability ranged from 40% to 94% in healthy individuals, with a value of 60%. While consuming meals did lower maximum serum concentrations by 10–15%, it was shown to have no impact on the drug's bioavailability.

3.2.4 Side effects:

- Chest discomfort.
- Dilated neck veins
- Extreme fatigue
- Irregular breathing
- Irregular heartbeat

4. RP-HPLC Method Development and Validation

4.1 Instrumentation

The chromatographic analysis was performed using **high-performance liquid chromatography (HPLC)** equipped with a photodiode array (PDA) detector.

Table 1 List of Instruments

S.No	Instrument	Model	Manufacturer
1	HPLC System	Alliance e2695	Waters Corporation
2	pH Meter	pH 700	Eutech Instruments
3	Analytical Balance	BSA224S-CW	Sartorius
4	Glassware (Pipettes, Beakers, Burettes)	Class-A	Borosil
5	Ultrasonicator	UCA 701	Unichrome

4.2 Chemicals and Reagents Table 2 Chemicals Used

S.No	Chemical	Grade	Manufacturer
1	Acetonitrile	HPLC	Merck
2	Water (Milli-Q)	HPLC	In-house
3	Triethylamine	AR	Merck
4	Ortho-phosphoric acid	AR	Merck

4.3 Determination of Detection Wavelength

The mixed standard solution of **Tamsulosin Hydrochloride** and **Dutasteride** was scanned between **200 and 400 nm** using a PDA detector.
The spectra showed an **isobestic point at 257 nm**, where both drugs exhibit equal absorptivity. Therefore, **257 nm** was selected as the detection wavelength for simultaneous estimation.

4.4 Preparation of Standard Solution

Accurately weighed **4 mg of Tamsulosin HCl** and **5 mg of Dutasteride** were transferred into a **10 mL volumetric flask**. The drugs were dissolved in diluent and sonicated until completely dissolved, and the volume was made up to the mark with diluent to obtain the **stock solution**.

Further dilution of **1 mL stock solution to 10 mL** produced working concentrations of:

- 40 ppm Tamsulosin HCl
- 50 ppm Dutasteride

2.1 Preparation of Sample Solution

Approximately **41 mg of the sample** containing Tamsulosin HCl and Dutasteride was weighed and transferred to a **10 mL volumetric flask**. The diluent was added and sonicated for **30 minutes** to dissolve the sample completely.

The solution was diluted to volume with diluent and filtered through a **0.45 µm membrane filter** before injection.

Table 3 4.6 Optimised Chromatographic Conditions

Parameter	Condition
Column	Luna Phenyl Hexyl (250 × 4.6 mm, 5 µm)
Mobile Phase	Acetonitrile: 0.1% TEA (pH 2.5 adjusted with OPA) (20:80)
Flow Rate	1.0 mL/min
Detection Wavelength	257 nm
Injection Volume	10 µL
Run Time	5 min

Under these conditions:

- Tamsulosin HCl retention time ≈ **2.126 min**
- Dutasteride retention time ≈ **3.754 min**
- Resolution ≈ **7.15**

4.7 System Suitability

System suitability was evaluated by injecting the standard solution before analysis. Acceptance criteria:

- Tailing factor ≤ 2
- Theoretical plates ≥ 2000
- Resolution between peaks ≥ 2

4.8 Method Validation

The developed method was validated according to guidelines of the **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use**.

Validation parameters included:

4.8.1 Specificity

Specificity was evaluated by comparing blank, standard, and sample chromatograms. No interference was observed at the retention times of the analytes.

4.8.2 Linearity

Linearity was studied at six concentration levels:

Table 4

Level	Tamsulosin (ppm)	Dutasteride (ppm)
I	10	12.5
II	20	25
III	30	37.5
IV	40	50
V	50	62.5
VI	60	75

A calibration curve of **peak area vs concentration** was plotted and the correlation coefficient was found to be **≥0.999**.

4.8.3 Accuracy

Accuracy was evaluated using **80%, 100%, and 120% recovery levels**.

The percentage recovery ranged between **98–102%**, indicating good accuracy.

4.8.4 Precision

Precision was evaluated as:

- System precision
- Method precision
- Intermediate precision

Six replicate injections were analyzed and the **%RSD was less than 2%**.

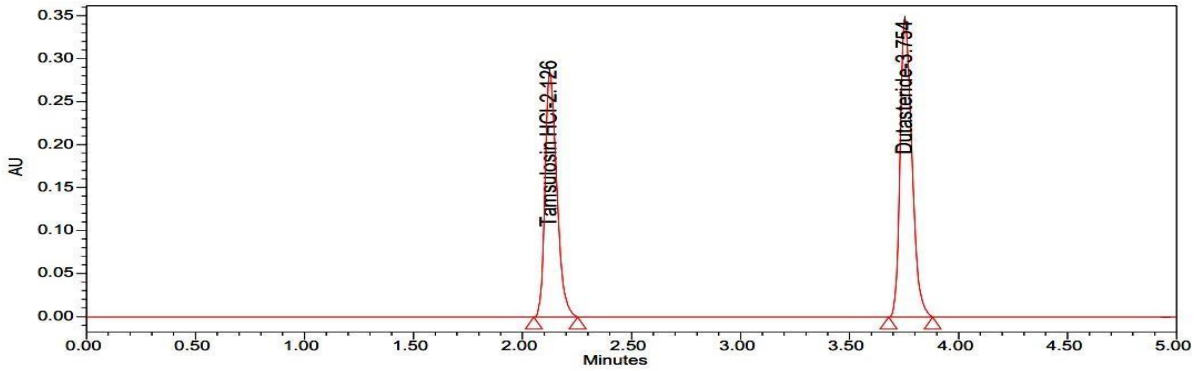
4.8.5 Robustness

Robustness was studied by deliberately varying experimental parameters:

- Flow rate (0.9–1.1 mL/min)
- Mobile phase composition

The method showed acceptable %RSD values (<2%).

4.8.6 Limit of Detection and Quantification



LOD and LOQ were calculated using:
LOD = 3.3 σ / S LOQ
= 10 σ / S

Table 5
Results:

Drug	LOD	LOQ
Tamsulosin HCl	0.48 µg/mL	1.60 µg/mL
Dutasteride	0.60 µg/mL	2.00 µg/mL

4.9 Forced Degradation Studies

Forced degradation studies were performed under the following conditions to evaluate the stability-indicating nature of the method:

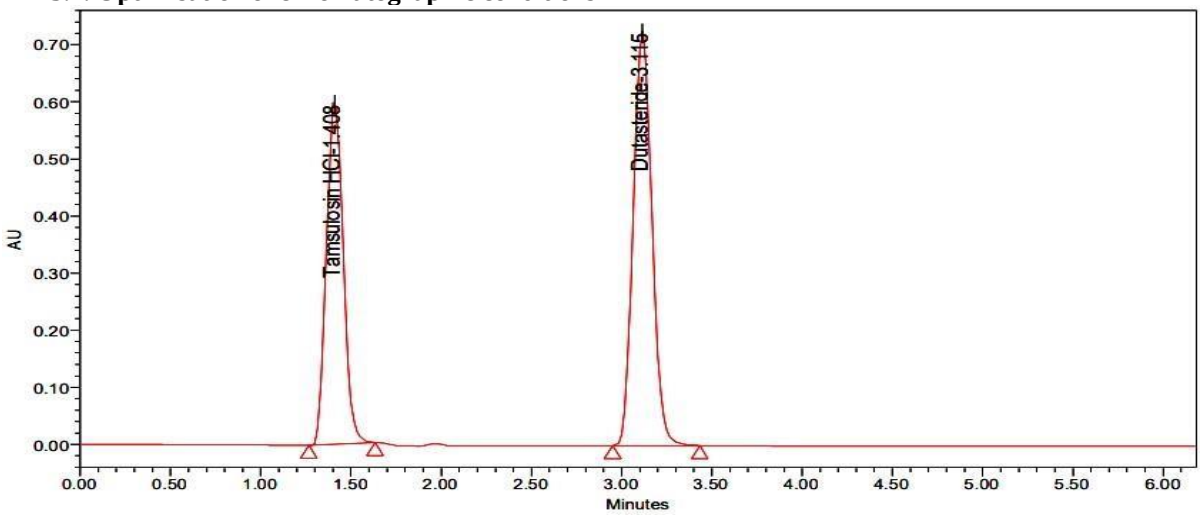
- Acid degradation (1N HCl)
- Alkali degradation (1N NaOH)
- Oxidative degradation (10% H_2O_2)
- Thermal degradation (105°C)
- Reduction degradation (sodium bisulphite)
- Photolytic degradation
- Hydrolytic degradation

The results indicated that degradation products did not interfere with the analyte peaks, confirming the stability-indicating capability of the method.

3. RESULTS AND DISCUSSION:

PDA - Spectrum

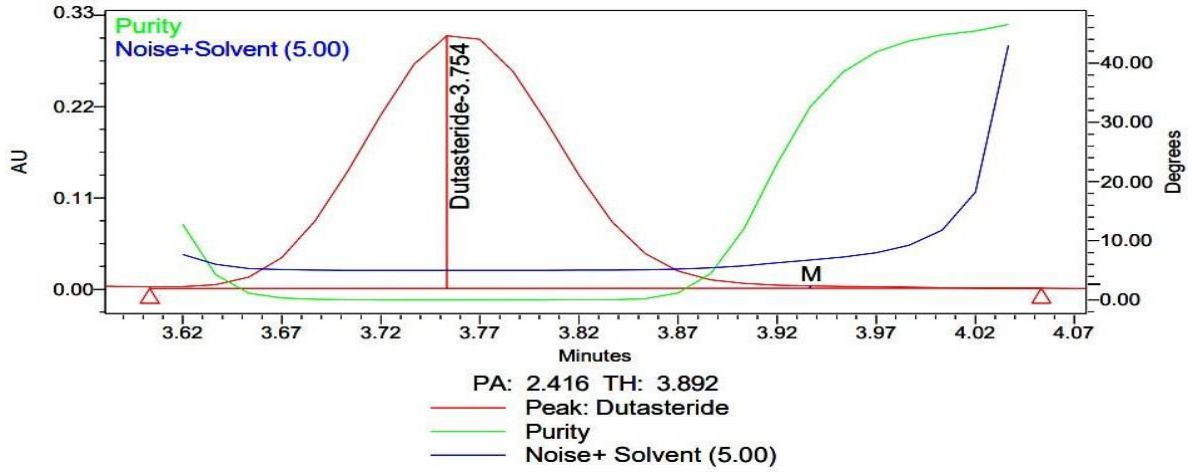
5.1. Optimisation of chromatographic conditions



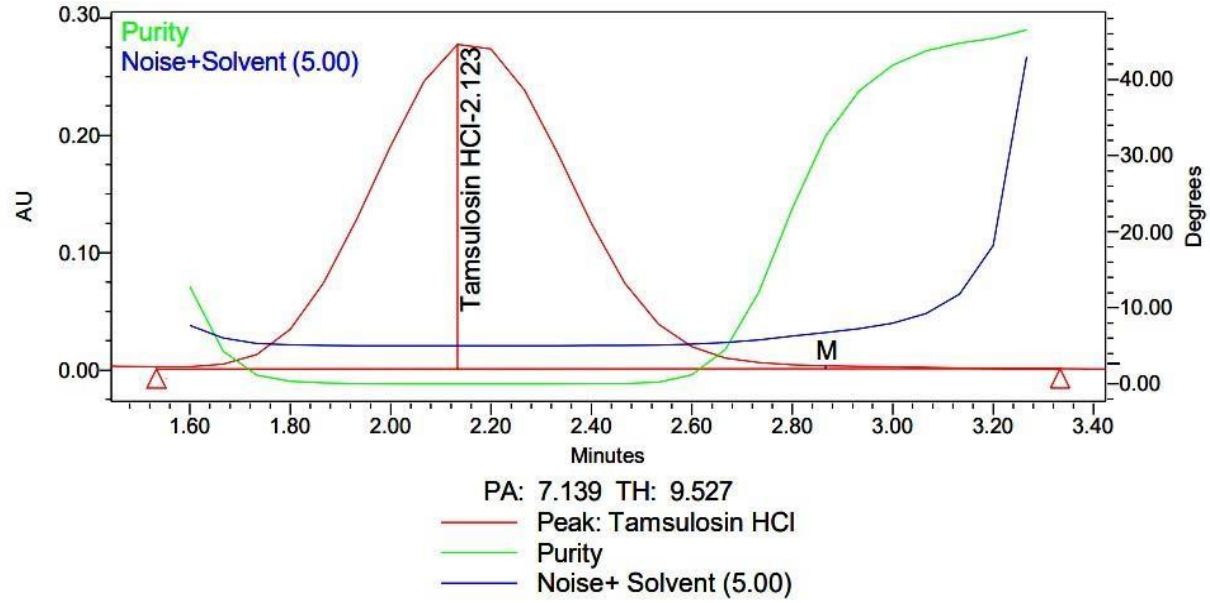
Optimized Chromatogram

5.2 optimized RP-HPLC separation of the drugs.

5.3 Purity Plot of Tamsulosin HCl



5.4 Photolytic degradation Chromatogram



4. CONCLUSION:

A simple, rapid, accurate, and precise analytical method was successfully developed for the simultaneous estimation of Tamsulosin Hydrochloride and Dutasteride using Reverse Phase High Performance Liquid Chromatography (RP-HPLC). The developed method proved to be economical, reliable, and suitable for routine quality control analysis.

The chromatographic conditions were optimized to obtain well-resolved peaks with acceptable retention times and good system suitability parameters. The mobile phase and solvents used in the method were easy to prepare, cost-effective, and contributed to reduced analysis time and operational simplicity.

The method was validated according to the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) with respect to specificity, precision, accuracy, linearity, robustness, limit of detection (LOD), and limit of quantification (LOQ). The validation results demonstrated that the method is reliable and reproducible for the quantitative estimation of both drugs.

Recovery studies confirmed that the excipients present in the pharmaceutical formulation did not interfere with the determination of the drugs, and the percentage recovery values were found to be within acceptable limits. This indicates that the developed method can be successfully applied for routine analysis of pharmaceutical formulations.

Furthermore, forced degradation studies under various stress conditions confirmed that the developed RP-HPLC method is stability-indicating. The method was able to effectively separate the drug peaks from their degradation products, demonstrating its specificity and suitability for

stability studies.

Therefore, the developed RP-HPLC method is simple, accurate, precise, and stability-indicating, and it can be effectively used for routine quality control and stability analysis of Tamsulosin Hydrochloride and Dutasteride in bulk drugs and pharmaceutical dosage forms.

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