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Quantitative estimation of drugs for erectile dysfunction and benign prostatic hyperplasia by high performance liquid chromatography: a review

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This review article explores the critical application of High-Performance Liquid Chromatography (HPLC) in analyzing medications for Erectile Dysfunction (ED) and Benign Prostatic Hyperplasia (BPH). HPLC is essential for the precise measurement of these drugs, whether assessed individually or within combination therapies. The review thoroughly examines various HPLC methodologies, encompassing both single-drug and simultaneous analysis techniques. It addresses the optimization of HPLC conditions and validation practices necessary for achieving reliable results. Key challenges in HPLC analysis are highlighted, including sensitivity issues and the need for specific adjustments in analytical procedures. The article discusses the influence of factors such as column types, mobile phases, and detection methods on HPLC performance. It offers detailed insights into optimizing parameters to enhance resolution and accuracy, providing practical guidance for researchers working with ED and BPH drugs. Moreover, the review outlines best practices for validating HPLC methods according to regulatory standards, which are crucial for maintaining the quality and reproducibility of analytical results. It also identifies potential areas for improvement, including enhancing method sensitivity and reducing analysis time. By emphasizing the importance of HPLC in maintaining high analytical standards for ED and BPH drug analysis, this review serves as a valuable resource for researchers, clinicians, and pharmaceutical companies, ultimately aiming to enhance drug management and improve patient outcomes through better analytical practices and innovative approaches.

Keywords: High performance liquid chromatography; erectile dysfunction; benign prostatic hyperplasia; chromatographic conditions; simultaneous estimation

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Introduction

Erectile dysfunction (ED) is frequently associated with Benign Prostatic Hyperplasia (BPH) and urinary symptoms, so men with BPH or urinary problems are more likely to experience ED as well (1). High-Performance Liquid Chromatography (HPLC) is a precise technique used to analyze these medications. For single estimation, HPLC can measure one drug at a time, such as Tadalafil for ED or Finasteride for BPH, to ensure accurate dosing and quality control. For simultaneous estimation, HPLC can analyze multiple drugs in a single test. For example, it can measure both Tadalafil (for ED) and Finasteride (for BPH) in one analysis, verifying their correct levels in combination therapy. Overall, HPLC is crucial for accurately measuring and ensuring the quality of medications for both ED and BPH, whether they are assessed individually or together (2).

The growing use of PDE5 inhibitors, including Sildenafil, Tadalafil, and Avanafil, has been accompanied by concerns regarding the quality and authenticity of pharmaceutical products. Counterfeiting and adulteration pose significant risks to consumer safety, necessitating the development of robust analytical methods. This review synthesizes recent studies on the analysis of these drugs, evaluating the effectiveness of various methods and their suitability for routine and quality control (QC) analysis (3). Oral phosphodiesterase type 5 inhibitors (PDE5i), like sildenafil, are the main treatment for erectile dysfunction (ED). Sildenafil, originally tested for heart disease, was found to improve erections and became FDA-approved for ED in 1998. It primarily inhibits the PDE5 enzyme, which is abundant in penile tissue, but also weakly affects PDE6, which can cause mild color vision issues. PDE5i work by enhancing the effects of nitric oxide, which increases cyclic guanosine monophosphate (cGMP) levels, leading to smooth muscle relaxation in the penis, improved blood flow, and sustained erections (4).

HPLC has become a cornerstone in pharmaceutical analysis due to its precision, accuracy, and versatility. Recent advancements have focused on optimizing HPLC methods for a variety of drugs including Tamsulosin, Dutasteride, Alfuzosin, Finasteride, Silodosin, and Solifenacin. This review evaluates the latest HPLC methodologies developed for these common drugs, comparing their effectiveness, sustainability, and application in pharmaceutical quality control.

Finasteride and dutasteride are both used to treat benign prostatic hyperplasia (BPH) by inhibiting 5α-reductase, which lowers dihydrotestosterone (DHT) levels responsible for prostate growth. Finasteride reduces circulating DHT by about 70%, whereas dutasteride nearly eliminates DHT levels in both serum and prostate. While finasteride is the first-line therapy, it can lead to sexual side

effects like decreased libido and ejaculatory dysfunction. Dutasteride is also effective, offering additional benefits in symptom improvement and reducing acute urinary retention (5).

Methodology

A literature review was conducted to evaluate various chromatographic strategies for the quantitative estimation of medications used in Benign Prostatic Hyperplasia and Erectile Dysfunction through High-Performance Liquid Chromatography. A thorough search was performed across multiple databases using the keywords "BPH," "ED," and "HPLC," resulting in a substantial number of articles. Publications from the period of 2017 to 2024 were then filtered. The inclusion criteria targeted articles published in English that discussed the analysis of drugs used for BPH and ED, either individually or simultaneously, utilizing HPLC. Tables 1 and 2 present an organizational chart summarizing the different chromatographic conditions employed by various authors in their analyses. Ultimately, forty-six relevant studies were selected: twenty-three focused on the analysis and development of analytical methods for ED drugs, while another twenty-three examined HPLC applications for BPH drugs.

Results and Discussion

1. Analytical methods for sildenafil: Ensuring authenticity and quality (Table 1)

Anjani Chaudhari *et al.* (2017), developed a method that spiked market samples, including capsules and tablets, with Sildenafil and Fluoxetine. This method demonstrated nearly 100% recovery, indicating high sensitivity and accuracy (6). Similarly, Emrah Dural (2020), introduced an HPLC method for detecting illegal Sildenafil in herbal products, finding that 74% of samples contained Sildenafil at varying concentrations. This study highlights the method's effectiveness in identifying adulterated products (7). In contrast, Mohamed A. Abdelshakour *et al*. (2021), focused on a rapid HPLC method for detecting Sildenafil along with other PDE5 inhibitors and their counterfeits in diverse products. This method underscored the prevalence of undeclared PDE5 inhibitors in products marketed as natural, emphasizing the need for comprehensive screening (8). Chowdhury Faiz Hossain *et al*. (2023), also detected Sildenafil citrate as an adulterant in all tested herbal preparations. This study highlights the widespread issue of contamination and the associated health risks, calling for more stringent regulatory measures (9). Miglena Smerikarova *et al.* (2021) & Panchumarthy Ravisankar *et al*. (2019), offer effective analysis of Sildenafil tablets. Smerikarova's method has a slight edge in terms of analysis speed due to its shorter run time. Ravisankar's method is emphasized for its cost-effectiveness, making it ideal for large-scale analysis (10-11).

Aminu Lawal Tama *et al*. (2020), detected Sildenafil in herbal aphrodisiac products from Northwestern Nigeria, finding contamination in 32% of samples. This study emphasizes the importance of monitoring for adulteration, which is critical for ensuring the quality and safety of herbal products (12). Hosam Eldin Dahshan *et al.* (2019), created a precise HPLC-UV method to analyze Sildenafil and Tramadol in biological fluids, revealing how Tramadol affects Sildenafil's pharmacokinetic parameters. This first study on their interaction provides essential insights for dose monitoring and side effect reduction (13). Amira H. Kamal *et al*. (2024), developed method that effectively identifies sildenafil in dietary supplements, addressing concerns about counterfeit products and ensuring accurate ingredient labeling. It provides a reliable tool for quality control and regulatory compliance, enhancing consumer safety by verifying the authenticity and consistency of sildenafil in supplements (14).

2. Analytical approaches for tadalafil: From stability to multi-drug analysis (Table 1)

Ashok Kumar *et al*. (2018), developed a new HPLC method for detecting both Sildenafil and Tadalafil in tablet formulations, offering improvements over previous bulk drug methods (15). Xiuwei Shen *et al*. (2020), created an HPLC method for detecting Tadalafil in rat plasma, highlighting the interaction with foods like grapefruit juice (16). Prashik S. Shimpi *et al*. (2020), used liquid-liquid extraction and chromatography to analyzeTadalafil and Sildenafil in spiked plasma, employing weighted least squares regression to address calibration challenges. Their method proved effective in overcoming common analytical issues (17). Vikram A. Madane *et al*. (2020), introduced an analytical method for Tadalafil that meets acceptance criteria but is noted for its high cost, pointing to a trade-off between precision and affordability (18). Mayara Aramburú Pinto *et al.* (2022), focused on the stability of Tadalafil and Sildenafil in counterfeit products, revealing significant degradation under photolytic conditions. This study highlights the risks associated with consuming degraded drugs and the importance of stability-indicating methods (19). Ahmed K. Kammoun *et al.* (2023), assessed the greenness of various methods using tools such as AGP, Eco-scale, and GAPI for simultaneous quantification of Finasteride and Tadalafil. They found that derivative spectrophotometric methods were more environmentally friendly and cost-effective compared to HPLC methods. This assessment emphasizes the importance of considering environmental impact alongside analytical performance (20). Amitkumar J *et al*. (2021), extended the Design of Experiments (DoE) to cover method validation, focusing on simplifying post-approval changes and technology transfers for simultaneous estimation of tadalafil and macitentan (21).

Table 1. HPLC chromatographic strategy map for erectile dysfunction drugs profiling

Drug detection dynamics: Individual/ Simultaneous estimation	HPLC chromatographic conditions	Quantification thresholds and Retention profiles (minutes)	References
Sildenafil citrate (SC) & Fluoxetine (FT)	Detector: UV Column: Chrome Budget C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: KH_2PO_4 buffer: 30 mM Triethylamine (pH 6 adjusted with *o*-phosphoric acid): Methanol (60:30:10 v/v) Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 20µL Wavelength: 230 nm Gradient system type: Isocratic mode	RT[1] - SC: 7.23, FT: 9.33 LOD[2] (µg/mL): 0.020 (SC), 0.016 (FT) LOQ[3] (µg/mL): 0.712 (SC), 0.621 (FT)	Anjani Chaudhari *et al.* (6)
Simultaneous analysis of degradation products and process-related impurities of Avanafil	Detector: PDA[4] Column: Inertsil ODS -3 (250 x 4.6 mm; 3 µm) Mobile phase A- 0.01M KH_2PO_4 buffer (pH 3.5) with 0.5% triethylamine: Acetonitrile (8.5:1.5 v/v) Mobile phase B- Water: Acetonitrile (2:8 v/v) Column temperature: 45 °C Flow rate: 1.2 mL/min Injection volume: 10µL Wavelength: 245 nm Gradient system type: Gradient elution mode	RT - deschloro impurity (0.84), acid impurity (0.94), dichloro impurity (1.31), dimer impurity (1.58), diamine impurity (1.63) LOD: 0.0348 µg/mL LOQ: 0.1037 µg/mL	Nitin Kumar *et al.* (25)
Sildenafil citrate (SC) & Tadalafil (TDL)	Detector: PDA Column: Purosphere Star C_8 (150 x 4.6 mm; 5 µm) Mobile phase- Water: Acetonitrile: Trifluoroacetic acid (65:35:0.1 v/v) Column temperature: 45 °C Flow rate: 1.0 mL/min Injection volume: 20µL Wavelength: 220 nm Gradient system type: Isocratic mode	RT - 3.73 (SC), 10.43 (TDL) LOD (µg/mL): 0.025 (SC), 0.05 (TDL) LOQ (µg/mL): 50 (SC), 10 (TDL)	Ashok Kumar *et al.* (15)
Sildenafil (SDF) & Tramadol (TMD)	Detector: UV Column: ODS Discovery HS C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- 10 mM Na_2HPO_4 (pH 7.5): Acetonitrile (45:55 v/v) Column temperature: Room temperature Flow rate: 0.8 mL/min Injection volume: 20µL Wavelength: 220 nm Gradient system type: Isocratic mode	RT - 4.2 (SDF), 7.3 (TMD) LOD (µg/mL): 0.02 (TMD), 0.01 (SDF) LOQ (µg/mL): 0.06 (TMD), 0.03 (SDF)	Hosam Eldin Dahshan *et al.* (13)

Vardenafil	Detector: UV Column: Eclipse XBD-C_8 (150 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: Aqueous solution of 0.012M Triethylamine + 0.020M *o*- phosphoric acid (40:60 v/v) Column temperature: 35-37 °C Flow rate: 0.5 mL/min Injection volume: 20µl Wavelength: 285nm Gradient system type: Gradient elution mode	RT - 9.4 LLOQ[5]: 100 ng/mL	Dr. Kumaraswamy Gandla *et al*. (27)
Tadalafil	Detector: DAD[6] Column: ZORBAX Eclipse XDB-C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: 0.2% Trifluoroacetic acid: Water (48 :10 : 42 v/v/v) Column temperature: 35°C Flow rate: 1 mL/min Wavelength: 286 nm	RT - 6.41 LLOQ: 100 ng/mL	Xiuwei Shen *et al*. (16)
Sildenafil citrate	Detector: UV Column: Welchrom C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- 10 mM Phosphate buffer: Acetonitrile (50:50 v/v) adjusted to pH 3.0 by *o*-phosphoric acid Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 20µl Wavelength: 230nm Gradient system type: Isocratic mode	RT - 3.473 LOD: 0.4221 µg/mL LOQ: 1.2792 µg/mL	Panchumarthy Ravisankar *et al*. (11)
Sildenafil (SIL), Vardenafil (VAR), Tadalafil (TAD), Dapoxetine (DAP), Yohimbine (YOH) and Sibutramine (SIB)	Detector: DAD Column: Infinity Lab Poroshell 120 EC-C_{18} (150 x 4.6 mm; 4 µm) Mobile phase- 0.030 M Ammonium acetate buffer with pH 3.0 adjusted with Formic acid: Acetonitrile (30:70 v/v) Column temperature: 40 °C Flow rate: 1 mL/min Injection volume: 10µl Wavelength: 230 nm Gradient system type: Isocratic/ Linear gradient mode	RT - YOH: 2.61, VAR: 4.90, SIL: 6.08, TAD: 11.02, DAP: 11.73, SIB: 12.25	Zdravka Zaharieva *et al*. (28)
Sildenafil	Detector: UV Column: LiChrosorb RP-18 (150 x 4.0 mm; 5 µm) Mobile phase- Acetonitrile: Methanol: 0.5% Triethylamine (15: 26: 59 v/v/v) Column temperature: 30 °C Flow rate: 1 mL/min Injection volume: 20µl Wavelength: 290 nm Gradient system type: Isocratic mode	RT - 10 LOD: 0.7 µg/mL LOQ: 2.2 µg/mL	Miglena Smerikarova *et al*. (10)

Avanafil	Detector: PDA Column: Inert sustain C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Water: Acetonitrile: Trifluoroacetic acid (65: 35: 0.1 v/v) Column temperature: 30 °C Flow rate: 1 mL/min Wavelength: 238 nm	RT - 10.77	M. V. Jadhav *et al*. (26)
Sildenafil	Detector: UV Column: Prontosil C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Methanol: Water (85:15 v/v) Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 10µl Wavelength: 230 nm Gradient system type: Isocratic mode	RT - 3.4 LOD: 1.61 µg/mL LOQ: 4.89 µg/mL	Aminu Lawal Tama *et al*. (12)
Tadalafil	Detector: UV Column: Eclipse XBD-C_8 (150 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: Aqueous solution of 0.012M triethyl amine + 0.020M *o*-phosphoric acid (40:60 v/v) Column temperature: 35-37 °C Flow rate: 0.5 mL/min Injection volume: 20 µl Wavelength: 285 nm Gradient system type: Gradient elution mode	RT - 9.4 LLOQ : 100 ng/mL	Prashik S. Shimpi *et al*. (17)
Sildenafil	Detector: UV Column: Reverse phase C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- 10mM Phosphate buffer with 0.1% triethylamine (pH 3.5): Acetonitrile (65:35 v/v) Column temperature: 35 °C Flow rate: 1 mL/min Wavelength: 293 nm Gradient system type: Isocratic mode	RT - 6.2 LOD : 1.9 ng/mL LOQ: 6.5 ng/mL	Emrah Dural. (7)
Tadalafil (TADA) & Macitentan (MACI)	Detector: PDA Column: Phenomenex gemini C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Methanol: 10 mM Ammonium formate (74.1 : 25.9 v/v) (pH: 6.8) Column temperature: 40 °C Flow rate: 0.94 mL/min Injection volume: 20 µl Wavelength: 260 nm Gradient system type: Isocratic mode	RT- TADA: 4.0, MACI: 7.2 LOD (µg/mL): 0.02 (MACI), 0.06 (TADA) LOQ (µg/mL): 0.12 (MACI), 0.37 (TADA)	Amitkumar J Vyas *et al*. (21)

Tadalafil	Detector: PDA Column: JASCO Crest Pack C_{18} (250 x 4.6 mm; 5 µm) Mobile phase A- Acetonitrile: Methanol (40:20 v/v) Mobile phase B- 0.01M Ammonium acetate in water adjusted pH 3.50 ± 0.05 with glacial acetic acid Column temperature: 25 °C Flow rate: 1 mL/min Injection volume: 10 µl Wavelength: 285 nm Gradient system type: Isocratic mode	RT- 5.1 LOD: 0.2 µg/ml LOQ: 0.6 µg/ml	Prajakta H. Patil *et al*. (22)
Sildenafil (SLD), Vardenafil (VAR), & Tadalafil (TAD) and their counterfeits Dapoxetine (DPX), Paroxetine (PRX), Citalopram (CTP), Tramadol (TRM) & Yohimbine (YHB)	Detector: UV Column: Phenomenex C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Water with 0.05% Formic acid: Acetonitrile Column temperature: 25 °C Flow rate: 1 mL/min Injection volume: 5 µl Wavelength: 230 nm Gradient system type: Gradient program mode	RT- TRM: 3.20, YHB: 3.60, VAR: 4.20, SLD: 4.94, CTP: 5.35, PRX: 6.14, DPX: 7.36, TAD: 10.40 LOD (µg/mL): 0.0093 (TRM), 0.0092 (YHB), 0.0130 (VAR), 0.0055 (SLD), 0.0293 (CTP), 0.0280 (PRX), 0.0251 (DPX), 0.0071 (TAD) LOQ (µg/mL):0.031 (TRM), 0.030 (YHB), 0.042 (VAR), 0.018 (SLD), 0.098 (CTP), 0.093 (PRX), 0.084(DPX),0.024 (TAD)	Mohamed A. Abdelshakour *et al.* (8)
Tadalafil	Detector: UV Column: Agilent Eclipse C_8 (150 x 4.6 mm; 5 µm) Mobile phase- Phosphate Buffer (pH 3.5): Acetonitrile: Methanol (50:40:10 v/v) Column temperature: 40 °C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 285 nm	RT- 3.450 LOD: 0.00068 ppm LOQ: 0.0043 ppm	Vikram A. Madane *et al*. (18)
Tadalafil (TAD) & Sildenafil (SIL)	Detector: DAD Column: Hypersil C_{18} (250 x 4.6 mm; 5 µm) The mobile phase is a 30:70 (v/v) mix of Solution A and Solution B. Solution A - Acetonitrile and Water (80:20 v/v) Solution B - Methanol and Triethylamine (0.3% pH 7.5, adjusted with *o*- phosphoric acid (57:43 v/v) Column temperature: 25 °C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 285 nm (TAD) & 292nm (SIL) Gradient system type: Isocratic mode	RT- 5.0 (TAD), 8.2 (SIL) LOD (ng/mL): 80 (TAD), 180 (SIL) LOQ (ng/mL): 120 (TAD), 270 (SIL)	Mayara Aramburú Pinto *et al*. (19)

Ambrisentan (AMB) & Tadalafil (TAD)	Detector: UV Column: Inertsil C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- KH_2PO_4 buffer, pH 3.0 adjusted with diluted *o*-Phosphoric acid: Methanol (50:50 v/v) Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 260 nm	RT- 7.077 (AMB), 3.807 (TAD) LOD (µg/mL): 0.117 (TAD), 0.0096 (AMB) LOQ (µg/mL): 0.357 (TAD), 0.00088 (AMB)	Syed Wajahat Shafaat *et al*. (24)
Sildenafil citrate (SIL) & Depoxetine HCl (DAP)	Detector: UV Column: BDS Hypersil C_{18} (250 x 4.6 mm; 5µm) Mobile phase- Buffer pH 4.0: Acetonitrile(40:60 v/v) Column temperature: 25 °C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 229 nm	RT- 3.5 (SIL), 4.5 (DAP) LOD (ppm): 5.59 (SIL), 3.78 (DAP) LOQ (ppm): 16.97 (SIL), 11.45 (DAP)	Shivanand Yadav *et al*. (23)
Sildenafil citrate	Detector: PDA Column: Phenomenex Luna (250 x 4.6 mm; 5µm) Mobile phase (A)- Acetonitrile: KH_2PO_4 (adjust to pH 2.5 with phosphoric acid) (10:90 v/v) Mobile phase (B)- Acetonitrile: KH_2PO_4 (adjust to pH 2.5 with phosphoric acid) (70:30 v/v) Column temperature: 40 °C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 293 nm Gradient system type: Gradient elution mode	RT- 13.6 LOD: 0.02 µg/mL LOQ: 0.07 µg/mL	Chowdhury Faiz Hossain *et al*. (9)
Finasteride (FIN) & Tadalafil (TAD)	Detector: PDA Column: XBridge TM C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: Phosphate buffer adjusted to pH 7 with 0.1% TEA (50 : 50 v/v) Flow rate: 1 mL/min Injection volume: 10 µl Wavelength: 221 nm (FIN) & 293 nm (TAD)	RT- 2.9 (TAD), 3.9 (FIN) LOD (µg/mL): 2.00 (FIN), 0.88 (TAD) LOQ (µg/mL): 6.5 (FIN), 2.9 (TAD)	Ahmed K. Kammoun *et al*. (20)
Sildenafil citrate	Detector: DAD Column: ODS HYPERSIL (250 x 4.6 mm; 5µm) Mobile phase- Methanol: KH_2PO_4 buffer 0.05M pH 3.5 (70:30 v/v): Triethylamine (0.3%) Flow rate: 1 mL/min Injection volume: 10 µl Wavelength: 290 nm Gradient system type: Isocratic mode	RT- 5.3 LOD: 0.490 µg/mL LOQ: 1.617 µg/mL	Amira H. Kamal *et al*. (14)

[1]Retention Time, [2]Limit Of Detection, [3]Limit Of Quantification, [4]Photo Diode Array, [5]Lower Limit Of Quantification, [6]Diode Array Detector

Prajakta Patil *et al*. (2021), applied a QbD-based, multivariate approach to identify critical process parameters (CPPs), aligning with FDA guidelines for estimation of Tadalafil Hydrochloride. QbD-based methods offer significant advantages in method development and validation, ensuring robustness and compliance with regulatory standards. These methods address complexities that traditional approaches might not cover (22). Shivanand Yadav *et al*. (2022), focused on Dapoxetine Hydrochloride and Tadalafil, the method uses distinct absorbance differences at specific wavelengths to achieve high specificity. This precision is crucial for accurate quantification in multi-component formulations, making specific detection methods valuable alongside other HPLC techniques for broader analysis (23). Syed Wajahat Shafaat *et al*. (2022), developed a cost-effective method for the routine analysis of Ambrisentan and Tadalafil in bulk and tablet forms. This approach is particularly suited for large-scale and routine analysis due to its cost-effectiveness and operational simplicity (24).

3. Avanafil analysis: Ensuring accuracy and reliability (Table 1)

Nitin Kumar *et al*. (2018), developed an RP-HPLC method for measuring Avanafil's breakdown products and impurities, ensuring accuracy and reliability (25). M. V. Jadhav *et al*. (2020), optimized chromatographic conditions to produce a sharp peak for Avanafil, enhancing column performance and resolution (26).

4. Vardenafil analysis (Table 1)

Dr. Kumaraswamy Gandla *et al*. (2020), developed an HPLC method for accurately measuring Vardenafil in human plasma with Sildenafil as an internal standard, meeting USFDA guidelines for bioavailability and bioequivalence studies. This method ensures reliable Vardenafil measurement in clinical settings (27).

5. General methodological advances (Table 1)

Zdravka Zaharieva *et al*. (2020), employed a gradient HPLC method for the separation of multiple PDE5 inhibitors (Sildenafil, Vardenafil, Tadalafil), along with other substances like Dapoxetine and Yohimbine. Gradient HPLC offers superior resolution and is advantageous when analyzing multiple PDE5 inhibitors simultaneously, compared to isocratic methods which may be less effective for complex samples (28).

Comparative analysis of HPLC techniques

Method effectiveness: The reviewed HPLC methods exhibit high effectiveness in detecting and quantifying pharmaceutical substances, with recent advancements enhancing accuracy and reliability. Anjani Chaudhari *et al.* and Emrah Dural's methods are particularly notable for their efficacy in detecting adulteration in various products.
Stability and impurity analysis: Methods that focus on stability and impurity analysis, such as those by Nitin Kumar *et al.* and M. V. Jadhav *et al*., provide valuable insights into drug degradation, which is crucial for maintaining drug quality.
Combination and multi-drug analysis: Advancements in methods for analyzing drug combinations, as demonstrated by Ashok Kumar *et al*. and Hosam Eldin Dahshan *et al*., are essential for understanding drug interactions and ensuring therapeutic efficacy.
Cost and environmental impact: Cost-effective methods from Panchumarthy Ravisankar *et al*. and Syed Wajahat Shafaat *et al*., along with environmentally friendly approaches highlighted by Ahmed K. Kammoun *et al*., reflect a growing emphasis on practical and sustainable analytical solutions.
Counterfeit detection: The research by Chowdhury Faiz Hossain *et al*. and Ahmed K. Kammoun *et al*. underscores the critical role of HPLC in detecting counterfeit drugs, highlighting the need for enhanced regulatory practices to manage such issues effectively.
Advanced techniques: The integration of QbD and DoE approaches, as seen in Amitkumar J *et al*. and Prajakta H. Patil *et al*. represents significant progress in method development, promoting robustness and regulatory compliance.

6. Cutting-edge HPLC approaches for Tamsulosin (Table 2)

Nagaraju *et al*. (2017), developed an isocratic RP-HPLC method with high recovery rates (98% for Tamsulosin and 100% for Dutasteride) and good precision. The method is effective for routine analysis in tablets, showing no interference from tablet excipients (29). Shereen A. Boltia *et al*. (2021), validated methods for Tamsulosin HCl and Deflazacort, including the active metabolite 21-Hydroxy Deflazacort. The methods were accurate, with a focus on assessing environmental impact and dissolution patterns (30). Kudupudi Chandrasekhar *et al*. (2021), developed an RP-HPLC method for Tamsulosin HCl and Dutasteride with propyl paraben as an internal standard. The method was specific, stability-indicating, and effective for routine quality control (31). All methods showed high accuracy and precision, with effective separation and analysis of Tamsulosin and Dutasteride. Methods by Nagaraju *et al*. and Kudupudi Chandrasekhar *et al*. focused on routine tablet analysis, while Shereen A. Boltia et al. also assessed dissolution and environmental impacts. The method developed by Vijay V. Rupapara *et al*. (2018), is noted for its simplicity, accuracy, and cost-effectiveness in simultaneously estimating Deflazacort and Tamsulosin in combined dosage forms. It offers high-resolution results with minimal complexity (32). W T. H. Al-Shammari *et al*. (2022), developed a robust HPLC method for Tamsulosin that stands out for its focus on storage stability, providing additional insights into the drug's shelf life (33). Kailash Redyy MV *et al*. (2023), developed a method for simultaneous estimation of Dutasteride and Tamsulosin in pharmaceutical formulations that well-suited for both routine quality control and stress-induced studies, with a focus on validating under various conditions (34).

Table 2. HPLC chromatographic strategy map for benign prostatic hyperlasia drugs profiling

Drug Detection Dynamics: Individual/Simultaneous estimation	HPLC Chromatographic conditions	Quantification thresholds and Retention Profiles (minutes)	References
Tamsulosin (TAM) & Dutasteride (DUT)	Detector: UV Column: Chromosil C_{18} (250 x 4.6 mm; 5µm) Mobile phase- Methanol: Acetonitrile: 2% *o*-phosphoric acid (60:20:20 v/v/v) Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 234 nm Gradient system type: Isocratic mode	RT- 2.19 (TAM), 5.19 (DUT) LOD (µg/mL): 2.83 (TAM), 3.29 (DUT) LOQ (µg/mL): 08.59 (TAM), 9.97 (DUT)	P. Nagaraju *et al*. (29)
Naftopidil	Detector: UV Column: ODS C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Potassium dihydrogen *o*-phosphate: Acetonitrile (35:65 v/v) Column temperature: 27 °C Flow rate: 1 mL/min Injection volume: 10 µl Wavelength: 232 nm Gradient system type: Isocratic mode	RT- 4.5 LOD: 0.094823 µg/mL LOQ: 0.287344 µg/mL	Shruti Bika *et al*. (51)
Doxazosin mesylate (DOX) & Finasteride (FIN)	Detector: UV Column: RESTEK Pinnacle II C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- 25 mM Ammonium acetate buffer (pH adjusted to 4.0 ± 0.05 with acetic acid): Acetonitrile (50:50 v/v) Column temperature: 25 °C Flow rate: 1 mL/min Wavelength: 230 nm Gradient system type: Isocratic mode	RT- 3.901 (DOX), 7.215 (FIN) LOD (µg/mL): 1.75 (DOX), 21.3 (FIN) LOQ (µg/mL): 5.30 (DOX), 64.6 (FIN)	Dillon Krotz *et al*. (39)
Alfuzosin	Detector: UV Column: Primesil C_8 (250 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: 0.05 *o*- phosphoric acid (40:60 v/v) pH 3.2 Column temperature: Ambient Flow rate: 0.7 mL/min Injection volume: 20 µl Wavelength: 242 nm	RT- 4.833 LOD: 0.4258 µg /mL LOQ:1.2896 µg /mL	Rahul R. Mishra *et al*. (35)

Terazosin (TER), Alfuzosin (ALF), Tamsulosin (TAM) & Doxazosin (DOX)	Detector: UV Column: Prontosil RP C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile : 50 mM phosphate buffer (30:70 v/v) with pH 3 adjusted by *o*-phosphoric acid Column temperature: 40 °C Flow rate: 1 mL/min (TER & ALF) & 1.5 mL/min (TAM & DOX) Injection volume: 20 µl Wavelength: 230 nm Gradient system type: Gradient elution mode	RT- 2.8 (TER), 3.1 (ALF), 4.9 (TAM), 6.9 (DOX) LOD (µg /mL):0.23 (TER), 0.17 (ALF), 0.20 (TAM), 0.28 (DOX) LOQ (µg /mL): 0.70 (TER), 0.53 (ALF), 0.60 (TAM), 0.84 (DOX)	M.I. Walash *et al*. (50)
Deflazacort & Tamsulosin HCl	Detector: UV Column: Hypersil BDS C_{18} (150 x 4.6 mm; 5µm) Mobile phase- Phosphate buffer (pH-4.0): Methanol (50:50 v/v) Column temperature: 25 ± 2°C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 227 nm	RT- 3.273 (DEF), 4.807 (TAM) LOD (µg/mL): 2.61 (DEF), 0.132 (TAM) LOQ (µg/mL): 7.90 (DEF), 0.40 (TAM)	Vijay V. Rupapara *et al*. (32)
Forced degradation study of Alfuzosin (ALF) & Dutasteride (DUT)	Detector: PDA Column: Phenomenex C_{18} (250 x 4.6 mm; 5µm) Mobile phase- Methanol: Water (80: 20 v/v) Column temperature: 50°C Flow rate: 1 mL/min Wavelength: 264 nm Gradient system type: Isocratic mode	RT- 4.18 (ALF), 2.94 (DUT) LOD (µg/mL): 0.07 (ALF), 0.06(DUT) LOQ (µg/mL): 0.21 (ALF), 0.17 (DUT)	P. D. Satpute *et al*. (36)
Finasteride & Tamsulosin HCl	Detector: UV Column: Bondapak C_{18} (300 x 3.9 mm; 10 µm) Mobile phase- 0.04 M *o*-phosphoric acid (pH 3.5 ± 0.2) adjusted with Triethylamine: Acetonitrile (50:50 v/v) Column temperature: Room temperature Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 215 nm	RT- 4.12 (TAM), 9.05 (FIN) LOD (µg/mL): 2.61 (FIN), 0.58 (TAM) LOQ (µg/mL): 7.92 (FIN), 1.76 (TAM)	Hany H. Monir *et al.* (40)
Dutasteride & Silodosin	Detector: PDA Column: Agilent C_{18} (250 x 4.6 mm; 5µm) Mobile phase- Methanol : Water (50:50 v/v) Column temperature: 40°C Flow rate: 1 mL/min Injection volume: 10 µl Wavelength: 280 nm Gradient system type: Isocratic mode	RT- 2.050 (SIL), 2.623 (DUT) LOD (µg/mL): 3.29 (SIL), 3.31 (DUT) LOQ (µg/mL): 9.89 (SIL), 9.95 (DUT)	Kattempudi Paljashuva *et al*. (44)

Finasteride	Detector: UV Column: Inertsil ODS C_{18} 3V (250 x 4.6 mm; 5µm) Mobile phase- Acetonitrile: Water (60:40 v/v) Flow rate: 1.1 mL/min Injection volume: 10 µl Wavelength: 245 nm Gradient system type: Isocratic mode	RT- 3.71 LOD: 1.783 ng/mL LOQ: 5.40 ng/mL	Shraddha T. Nemane *et al*. (41)
Alfuzosin (ALF) & Solifenacin (SOL) along with their official impurities (imp)	Detector: UV-DAD Column: XBridge C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile : Phosphate buffer (pH 8) : Triethylamine (60 : 40 : 0.02 v/v/v) Column temperature: Ambient Flow rate: 1.3 mL/min Wavelength: 210 nm Gradient system type: Isocratic mode	RT- 1.672 (ALF imp-D) , 2.258 (SOL imp-I), 3.823 (ALF), 5.031 (SOL), 7.600 (SOL imp-A) LOD (µg/mL) : 0.508 (ALF imp-D), 0.237 (SOL imp-I);0.354 (SOL imp-A) LOQ (µg/mL): 1.539 (ALF imp-D), 0.719 (SOL imp-I); 1.072 (SOL imp-A)	Mahmoud A. Tantawy *et al*. (38)
Alfuzosin (ALF) & Dutasteride (DUT)	Detector: UV Column: XTerra C_{18} (150 x 4.6 mm; 5µm) Mobile phase- $NH_4H_2PO_4$ buffer (pH 6.5): Methanol (25:75 v/v) Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 246 nm Gradient system type: Isocratic mode	RT- 2.14 (ALF), 4.26 (DUT) LOD (µg/mL): 1.41 (ALF), 0.71 (DUT) LOQ (µg/mL): 4.27 (ALF), 2.14 (DUT)	Keerthana Diyya (48)
Alfuzosin (ALF) enantiomers & Solifenacin (SOL)	Detector: UV-DAD Column: Phenomenex Lux Cellulose 2 CSP (150 x 4.6 mm; 5 µm) Mobile phase- Ethanol: Phosphate buffer pH 4 (30:70 v/v) Flow rate: 0.5 mL/min Injection volume: 20 µl Wavelength: 215 nm	RT- 1.219 (ALF Enantiomer 1), 1.535 (ALF Enantiomer 2); 2.441 (SOL) LOD (µg/mL): 0.982 (ALF Enantiomer 1), 0.870 (ALF Enantiomer 2), 0.820 (SOL) LOQ (µg/mL): 2.977 (ALF Enantiomer 1), 2.637 (ALF Enantiomer 2), 2.486 (SOL)	Mina Wadie *et al*. (37)
Tamsulosin HCl (TAM) & Dutasteride (DUT)	Detector: PDA Column: Kromasil C_{18} (250 x 4.6 mm; 5µm) Mobile phase- Phosphate buffer: Acetonitrile (35: 65 v/v) Column temperature: 40°C Flow rate: 1 mL/min Injection volume: 10 µl Wavelength: 225 nm Gradient system type: Isocratic mode	RT- 2.804 (TAM), 12.914 (DUT) LOD (µg/mL): 0.13 (TAM), 0.17 (DUT) LOQ (µg/mL): 0.4 (TAM), 0.5 (DUT)	Kudupudi Chandrasekhar *et al*. (31)

Tamsulosin HCl (TAM) & Deflazacort (DEF)	Detector: DAD Column: C-8 ACE Generix (250 x 4.6 mm; 5 µm) Mobile phase- 0.2% Acetic acid in Water : Ethanol (50:50 v/v) Column temperature: 35°C Flow rate: 0.8 mL/min Injection volume: 20 µl Wavelength: 225 nm (TAM) & 245 nm (DEF)	RT- 4.2 (TAM), 6.9 (DEF) LOD (µg/mL): 0.04 (TAM), 0.10 (DEF) LOQ (µg/mL): 0.12 (TAM), 10.30(DEF)	Shereen A. Boltia *et al.* (30)
Dutasteride	Detector: UV Column: BDS HYPERSIL C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: Water: Methanol (75:10:15 v/v/v) Column temperature: 20°C Flow rate: 0.7 mL/min Injection volume: 20 µl Wavelength: 274 nm	RT- 8.34 LOD: 5.2724 µg/mL LOQ: 10.977 µg/mL	Abhilasha V.Deshmukh *et al*. (45)
Tamsulosin	Detector: UV Column: C_{18} (250 x 4.6 mm; 5 µm) Mobile phas - 0.05N KH_2PO_4: Acetonitrile (55:45 v/v) Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 275 nm	RT- 10 LOD: 0.00053 µg/mL LOQ: 0.0016 µg/mL	W T. H. Al-Shammari *et al*. (33)
Dutasteride	Detector: DAD Column: XTerra C_{18} (150 x 4.6mm; 5µm) Mobile phase- Phosphate buffer pH adjusted to 3.0 by *o*-phosporic acid: Acetonitrile (20: 80 v/v) Flow rate: 0.8 mL/min Injection volume: 20 µl Wavelength: 280 nm Gradient system type: Isocratic mode	RT- 2.003 LOD: 3.14 µg/mL LOQ: 10.05 µg/mL	Y. Rajendra Prasad *et al*. (47)
Silodosin (SIL) & Solifenacin (SOL)	Detector: UV Column: X Bridges C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile: Methanol: Potassium dihydrogen *o*-phosphate buffer pH 4.5 (50:20:30 v/v/v) Column temperature: 27 ± 2°C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 210 nm Gradient system type: Isocratic mode	RT- 3.626 (SIL), 5.754 (SOL) LOD (µg/mL): 0.057 (SIL), 0.079 (SOL) LOQ (µg/mL): 0.174 (SIL), 0.240 (SOL)	Shubham Dhiman *et al*. (42)

Dutasteride & Silodosin	Detector: PDA Column: Xterra Symmetry C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- 0.1N K_2HPO_4: Acetonitrile (20: 80 v/v) Column temperature: 20°C Flow rate: 0.7 mL/min Injection volume: 20 µl Wavelength: 265 nm Gradient system type: Isocratic mode	RT- 2.003 (DUT), 3.377 (SIL)	Kadali Jagadeesh *et al*. (43)
Dutasteride	Detector: UV Column: Phenomenex Luna C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- Acetonitrile :Water (80:20 v/v) Column temperature: 25°C Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 242 nm	RT- 5.9 LOD: 0.242 µg/mL LOQ: 0.732 µg/mL	Mahtab Ali *et al.* (46)
Dutasteride (DUT) & Tamsulosin HCl (TAM)	Detector: PDA Column: BDS Hypersil C_{18} (250 x 4.6 mm; 5 µm) Mobile phase- CH_3COONH_4: Methanol (55:45 v/v) Column temperature: 30°C Flow rate: 0.8 mL/min Injection volume: 20 µl Wavelength: 254 nm	RT- 3.153 (DUT), 4.3 (TAM) LOD (µg/mL): 3.135 (DUT) 4.305 (TAM) LOQ (µg/mL): 3.120 (DUT) 4.279 (TAM)	Mule Venkata Kailashreddy *et al.* (34)
Dutasteride (DUT) & Silodosin (SIL)	Detector: DAD Column: XBridge C_{18} (150 x 4.6 mm; 5 µm) Mobile phase- Methanol: Phosphate buffer pH 6.0 (77: 23 v/v) Column temperature: Ambient Flow rate: 1 mL/min Injection volume: 20 µl Wavelength: 245 nm Gradient system type: Isocratic mode	RT- 2.36 (SIL), 4.98 (DUT)	Mina Wadie *et al.* (49)

7. Innovations in HPLC for alfuzosin: From rapid analysis to green methods (Table 2)

Rahul R. Mishra *et al.* (2017), developed a rapid RP-HPLC method for Alfuzosin, effective even in the presence of degradation products. However, the use of acetonitrile, a hazardous and costly solvent, was noted (35). P. D. Satpute *et al*. (2018), evaluated stability of Alfuzosin under various stress conditions, showing minimal degradation and effective separation from degradation products (36). Mina Wadie *et al.* (2021), introduced a green HPLC method using minimal ethanol, offering sustainability and improved resolution for separating Alfuzosin enantiomers, which reduced environmental impact compared to traditional methods using acetonitrile (37).

The methods varied in solvents and sustainability. Rahul R. Mishra *et al*. used acetonitrile, while Mina Wadie *et al*. provided a greener alternative with ethanol. Both methods demonstrated high precision, but Wadie's approach is more eco-friendly.

Mahmoud A. Tantawy *et al*. (2020), created a stability-indicating HPLC method for analyzing alfuzosin and solifenacin in co-formulated capsules. The method accurately identified degradation products and assessed stability, with recoveries of 100.47% and 100.15% (38).

8. HPLC methodologies for Finasteride (Table 2)

Dillon Krotz *et al*. (2017), validated an RP-HPLC method for finasteride in combination with doxazosin. The method was accurate for measuring both drugs in bulk and formulations, highlighting its effectiveness for benign prostatic hyperplasia treatment (39). Hany H. Monir *et al*. (2020), developed a stability-indicating HPLC method for Finasteride and Tamsulosin HCl, distinguishing active ingredients from degradation products (40).

Krotz's method focused on a combination therapy, while Hany H. Monir *et al*. emphasized stability and degradation product analysis.

Shraddha T. Nemane *et al.* (2019), developed an isocratic HPLC method for Finasteride with 97-99% recovery indicating accurate and precise method (41).

9. Simultaneous analysis of Silodosin: Advances and optimization (Table 2)

Shubham Dhiman *et al*. (2023), used a Quality by Design (QbD) approach for the simultaneous estimation of Silodosin and Solifenacin, optimizing resolution and theoretical plate numbers. This method is noted for its cost-effectiveness and accuracy (42). Kadali Jagadeesh *et al*. (2023), developed a robust method for simultaneous analysis of Dutasteride and Silodosin, emphasizing its suitability for quality control and stability studies (43). The method reported by Kattempudi Paljashuva *et al*. (2019), demonstrated a recovery rate between 99-101%, confirming its accuracy, precision, and suitability for pharmaceutical analysis of Silodosin and Dutasteride. The method is rapid and economical (44).

10. HPLC methodologies for Dutasteride (Table 2)

The method developed by Abhilasha V. Deshmukh *et al*. (2021), for Dutasteride is reliable for content uniformity and quality control, adhering to ICH guidelines. It is precise and effective for single-component formulations (45). Mahtab Ali *et al*. (2023), proposed a simple and precise method for Dutasteride using Dexamethasone as an internal standard. The method is economical and effective for routine quality control with added emphasis on reducing systematic errors through the use of an internal standard (46). Rajendra Prasad Y *et al.* (2022), proposed a simple and economical HPLC method for Dutasteride, effective for clinical and pharmacokinetic studies, and well-suited for bulk and pharmaceutical dosage forms (47). Keerthana Diyya (2020), presented an RP-HPLC method for Alfuzosin and Dutasteride, showing improved analysis time and specificity, with a focus on cost-effectiveness (48). Mina Wadie *et al*. (2024), offered two versatile methods for Dutasteride and Silodosin, utilizing UV and fluorometric detection. The fluorometric method showed high sensitivity and environmental benefits, proving superior to traditional HPLC methods (49).

11. General methodological advances (Table 2)

M.I. Walash *et al*. (2017), developed a method for simultaneous analysis of four α-adrenergic blockers - terazosin, alfuzosin, tamsulosin, and doxazosin using moxifloxacin as an internal standard. The use of 30% acetonitrile and 0.1% TEA optimized separation and peak symmetry, offering excellent resolution and reasonable elution times (50). The method developed by Shruti Bika *et al*. (2017), achieved reliable quantification with minimal deviation, emphasizing its robustness for Naftopidil without the complexities of multiple-drug analysis (51).

Comparative analysis of HPLC techniques

Accuracy and precision: evaluating the reliability of recent methods

Most methods demonstrated high accuracy and precision, particularly those developed by Nagaraju *et al*. Kudupudi Chandrasekhar *et al*. and Shubham Dhiman *et al*. For Tamsulosin and Dutasteride, isocratic RP-HPLC methods have proven reliable. The accuracy of these methods is further supported by high recovery rates and minimal interference from excipients.

Sustainability and environmental impact: *green vs. traditional methods*

Recent advancements have increasingly focused on sustainability. Wadie *et al*.'s green HPLC method using ethanol for Alfuzosin is a notable example of reducing environmental impact. Methods incorporating acetonitrile, while effective, are less favorable due to cost and environmental concerns.

Stability and stress-induced analysis: assessing drug degradation and stability

Stability-indicating methods, such as those by P. D. Satpute *et al.* and Hany H. Monir *et al*. are essential for assessing drug stability under various conditions. These

methods effectively separate drugs from degradation products, ensuring accurate quality control.

Cost-effectiveness: balancing precision with economic viability

While many methods offer high accuracy and precision, cost-effectiveness varies. Methods using costly solvents like acetonitrile, as noted by Rahul R. Mishra *et al*. are less economical. Conversely, methods employing greener solvents or more economical approaches, such as those by Keerthana Diyya and Y. Rajendra Prasad *et al*. offer significant cost benefits.

Versatility and application: emerging techniques and technologies in HPLC

Versatile methods, such as those by Mina Wadie *et al*. and Shubham Dhiman *et al*. demonstrate the ability to analyze multiple drugs simultaneously and adapt to various pharmaceutical formulations. This versatility is crucial for comprehensive pharmaceutical quality control.

Abbreviations

RT: Retention Time, µg/mL: micrograms per millilitre, ppm: parts per million, ng/mL**:** nanograms per millilitre, LOD: Limit of Detection, LOQ: Limit of Quantification, LLOQ: Lower Limit of Quantitation

Conclusions

High Performance Liquid Chromatography is adept at managing complex analyses, particularly when dealing with combination of drugs where two drugs are combined together such as ED and BPH medications. This ability facilitates the effective management of intricate treatment plans. Recent advancements in analytical methods for PDE5 inhibitors have significantly improved the detection and analysis of these drugs. The HPLC methods offer high sensitivity and accuracy, derivative spectrophotometry presents a cost-effective and environmentally friendly alternative. The review highlights the importance of advancing current methodologies and exploring innovative technologies to improve the analysis of ED and BPH drugs together. In summary, this review emphasizes HPLC's vital role in ensuring precise and high-quality drug analysis for ED and BPH treatments for various ailments, offering valuable guidance for refining and validating analytical techniques. Ongoing research and development is essential to address challenges related to cost, environmental impact, and method robustness, ensuring the safety and efficacy of pharmaceutical products as per ICH guidelines.

This review highlights how important HPLC is for analyzing medications used to treat erectile dysfunction (ED) and benign prostatic hyperplasia (BPH). HPLC helps accurately measure the active ingredients in drugs like sildenafil and tadalafil for ED, and finasteride and tamsulosin for BPH. Getting the correct amount of these ingredients is essential for making sure the medications work well and are safe for patients. Accurate measurement of these active ingredients is crucial because it ensures that each medication has the right dose. This is particularly important for ED and BPH treatments, where precise dosing is needed to achieve the best results and avoid side effects.

Overall, this review emphasizes the key role of HPLC in making sure that drugs for ED and BPH are properly measured and controlled, contributing to their effectiveness and safety for patients.

Recent developments in HPLC methodologies have led to significant improvements in accuracy, sustainability, and cost-effectiveness for analyzing pharmaceuticals. The choice of method depends on the specific needs of accuracy, environmental impact, and economic considerations. Advances in greener solvents as a part of green chromatography and versatile approaches are paving the way for more sustainable and efficient pharmaceutical analyses. Future research should continue to focus on enhancing these methods to meet evolving industry standards and regulatory requirements.

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Conflict of interest

The authors declare no conflicts of interest.

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