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COMPREHENSIVE REVIEW OF ANALYTICAL METHODS FOR THE DETERMINATION OF PRAZOSIN HYDROCHLORIDE IN PHARMACEUTICAL FORMULATION

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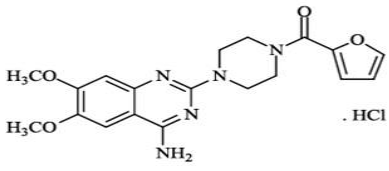
ABSTRACT[1]

Prazosin Hydrochloride (Prazosin HCl) is a selective α1-adrenergic receptor antagonist widely used in the management of hypertension, benign prostatic hyperplasia, and post-traumatic stress disorder-related nightmares. Accurate and reliable analytical methods are essential for the quality control, formulation development, stability assessment, and pharmacokinetic studies of Prazosin HCl. This review provides a comprehensive overview of the analytical techniques reported for the determination of Prazosin HCl in bulk drug substances, pharmaceutical formulations, and biological matrices. Various chromatographic methods, including High-Performance Liquid Chromatography (HPLC), Ultra-Performance Liquid Chromatography (UPLC), High-Performance Thin-Layer Chromatography (HPTLC), and Thin-Layer Chromatography (TLC), are critically discussed. In addition, spectroscopic methods such as UV–Visible spectrophotometry and liquid chromatography–mass spectrometry (LC–MS/MS) are reviewed. Method development parameters, validation characteristics, sensitivity, specificity, accuracy, precision, robustness, and regulatory considerations based on International Council for Harmonisation (ICH) guidelines are highlighted. Comparative evaluation of the reported methods reveals their applicability in routine quality control and research settings. This review aims to serve as a valuable reference for researchers, analysts, and pharmaceutical scientists involved in the development and validation of analytical methods for Prazosin HCl.

KEYWORDS: Prazosin Hydrochloride, HPLC, UV Spectrophotometry, Analytical Method Development, Method Validation, Pharmaceutical Analysis, Quality Control.

INTRODUCTION[2]

Piperazine, 1–(4–amino–6,7–dimethoxy–2–quinazolinyl)–4–(2–furanyl) mono-hydrochloride (carbonyl) is the chemical name for Prazosin HCl.



One of the first compounds in a new class of antihypertensive treatments, it is a powerful and selective α1-adrenergic receptor antagonist and is a member of the quinazoline derivative class. Vasodilation, which is caused by inhibiting α1- adrenergic receptors in blood vessels, lowers peripheral resistance and blood pressure while keeping the heart rate steady and having no effect on sympathetic nervous system activity. This drug is frequently used to treat circulatory failure brought on by scorpion stings, hypertension, and refractory pulmonary edema. It also has a major impact on improving urine

flow and decreasing retention, which decreases irritative and obstructive urinary symptoms.

Prazosin is useful in treating urinary hesitancy brought on by benign prostatic hyperplasia (BPH) because alpha-1 receptors control the constriction of the prostate and ureters. Furthermore, prazosin has been shown to help people with post-traumatic stress disorder (PTSD) sleep better by lowering trauma-related dreams and sleep disturbances. Various analytical methods have been explored for the Quantitation of prazosin, including radio receptor assays, voltammetry, differential pulse polarography, and fluorimetric analysis.

Several spectrophotometric techniques have also been developed to detect prazosin in biological samples and pharmaceutical formulations. To address these challenges, this study aims to develop and validate a simple, sensitive, rapid, and precise UV spectroscopic technique for the quantitative analysis of Prazosin HCl. Unlike existing methodologies, this UV spectrophotometric method is more straightforward and efficient, offering a practical alternative to high Performance liquid chromatography (HPLC) techniques recommended by the United States Pharmacopeia (USP) and British Pharmacopeia (BP).

MECHANISMOF ACTION[17,19]

Prazosin is an alpha-1 adrenergic receptor antagonist. Alpha-1-receptors are present on smooth muscle, as in the blood vessel walls, the prostate, urethra, iris dilator muscle, and brain. Alpha 1 antagonists cause smooth muscle relaxation, which can cause a decrease in blood pressure by decreasing systemic vascular resistance. This medication can also cross the blood-brain barrier. This mechanism allows for cognitive effects and hence its use in PTSD and PTSD-associated nightmares.

CYP450 enzymes hepatically metabolize this medication. The half-life is approximately 2.5 hours. however, it persists longer in chronic renal failure and congestive heart failure. renal adjustments are necessary for chronic kidney disease or patients on hemodialysis or peritoneal dialysi.

FLOW CHART[18]

PRAZOSIN
↓
Blocks α_1-Adrenergic Receptors
↓
↓ Intracellular Ca^{2+} Release
↓
Relaxation of Smooth Muscle
↓
Vasodilation
↓
↓ Peripheral Vascular Resistance
↓
↓ Blood Pressure

PHYSIOCHEMICAL PROPERTIES[16]

Drug profile:

Molecular Formula: $C_{19}H_{21}N_5O_4$

Molecular Weight: 383.4011 g/mol

IUPAC Name: 2-[4-(furan-2-carbonyl) piperazin-1-yl]-6,7-Dimethoxyquinazoline - 4 – amine

Category: Anti-hypertension (High blood pressure)

Solubility: Soluble in organic solvents like methanol and DMF

Slightly soluble in water

Appearance: whitetooff-white crystallinepowder

USES: Hypertension

ADVERSE EFFECTS: Dizziness, Headache, Drowsiness, Weakness, Nausea.

ADMINISTRATION: Prazosin is administered orally as tablets lor capsules.

AVAILABLE FORMULATION OF PRAZOSIN IN MARKET IN INDIA[5,6,7]

Brand Name	Manufacturer	Strength
Minipress	Pfizer	2.5 mg, 5 mg
Prazopress	Sun Pharmaceutical Industries	1 mg, 2 mg
Prazopress XL	Sun Pharmaceutical Industries	2.5 mg, 5 mg
Renopress XL	La Renon Healthcare	2.5 mg, 5 mg
Prazocip XL	Cipla	2.5mg
Cyber-CR	Raptakos Brett & Co.	2.5 mg, 5 mg
Prazolin	CMR Life Sciences	2.5 mg, 5 mg
Prazopol	Medipol Pharmaceuticals	5mg
Prazowin	Various manufacturers	5mg

Pharmacokinetics

The pharmacokinetic profile of Prazosin Hydrochloride (HCl) is characterized by the following key parameters:

Absorption: Well absorbed after oral administration, with bioavailability approximately 60%.

Distribution: Highly protein-bound (92–97%), primarily to alpha-1-acid glycoprotein.

Metabolism: Extensively metabolized in the liver via de methylation and conjugation.

Elimination: Primarily excreted via bile and feces (>90 %), with a small amount excreted in the urine.

Halflife: Approximately 2 to 3 hours, with a long duration of anti-hypertensive effect, typically 10hours.

TOXICITY[28]

There is no direct toxicity with this medication. High doses and overdoses could lead to hypotension, and patients should be supported clinically with volume resuscitation if necessary or pressor support.

The literature reports a case of an overdose of prazosin in a pediatric patient with hypotension, which was refractory to volume resuscitation, epinephrine, and norepinephrine support. This patient had concomitant ingestion with naproxen and acetaminophen. Given the hepatic metabolism of both acetaminophen and prazosin, this likely led to the prolonged clearing of the medication. The patient did respond to vasopressin

ANALYTICAL METHODS

UV Spectroscopy

1. UV spectrophotometric method was developed and validated for Prazosin HCl in active pharmaceutical ingredient and tablet dosage form have been developed and validated as per ICH guidelines.A 0.01N HCl solution was used as a diluent. The current study estimated the amount of Prazosin HCl using absorbance values at 246 nm. Detection limit., quantitation limit [LOQ], linearity, accuracy, and precision have all been statistically validated for the analysis results. A correlation coefficient of 0.9965 indicated that the procedure was linear in the concentration range of 2–10 µg/mL.[9]

2. To develop a simple UV–Vis spectrophotometric method for prazosin quantification in phosphate buffer pH 7.4. A double-beam UV spectrophotometer was used with methanol for stock solution (1000 µg/mL) and phosphate buffer pH7.4 as diluent. Calibration standards (2–10 µg/mL) were analyzed at 257nm.Validation included intra/inter-day precision (6 µg/mL, n=6), accuracy (80-120% recovery), specificity (blank/placebo/stressed samples), robustness (±1 nm wavelength, ±0.2 pH), and stability (0-48 h).[8]

3. UV–Vis spectrophotometric method for prazosin quantification in methanol.Reported the absorbance values at 246 nm were used for the estimation of prazosin. the results of analyses have been validated for linearity, accuracy, precision, LOD, LOQ. The method was found the linearity range of 5-80 µg/ml with correlation coefficient of 0.9999.[10]

4.This work was aimed at creating a new, fast, and accurate UV spectrophotometric method for quantifying prazosin hydrochloride in pure and tablet dosage forms. A phosphate buffer solution of pH 6 was used as a diluent. The highest absorbance of prazosin hydrochloride was measured at 247 nm, and the linearity ranged from 2 to 8µg/ml. The regression equation for prazosin hydrochloride was y= 0.087x + 0.236, with a correlation value 0.987. The percentage of recovery ranged from 99.6 to 101%. The relative standard deviation for intraday precision and interday precision was determined to be less than 2. The LOD and LOQ of prazosin hydrochloride were determined to be 0.0375 and 0.113 µg/mL, respectively.[13]

5. Prazosin Hydrochloride (PRZ) is an antihypertensive agent which is one of the leading marketed drugs in the world. A rapid, specific and economic UV spectrophotometrically method has been developed using methanol as a solvent to determine the PRZ content in bulk and pharmaceutical dosage formulations. At a predetermined Λ max of 2 nm, it was proved linear in the range of 1-5 µg/mL, and exhibited good correlation coefficient (R 2 =0.999) and excellent mean recovery. This method was successfully applied to the determination of PRZ content in one marketed brand from India and the results were in good agreement with the label claim. The method was validated statistically and by recovery studies for linearity, precision, accuracy, ruggedness, robustness, LOD and LOQ. The obtained results proved that this method can be employed for the routine analysis of PRZ in bulks as well as in the commercial formulations.

RP-HPLC

1. RP-HPLC Method development and validation for simultaneous estimation of prazosin and polythiazide In this method Symmetry C18 column (150mm×4.6mm, 5?m particle size), Waters Alliance e2695 HPLC system with PDA detector and the mobile phase contained a mixture of 0.01M Potassium dihydrogen orthophosphate buffer (pH adjusted to 3.48 with orthophosphoric acid) and Acetonitrile (50:50, v/v) was used. The flow rate was set to 1mL/min with the responses measured at 265nm. The retention time of Prazosin and Polythiazide was found to be 2.989min and 2.134min respectively with resolution of 5.1. Linearity was established for Prazosin is 25-150µg/mL and for Polythiazide is 6.25-37.5µg/mL with correlation coefficients (r2=0.999). The percentage recoveries for Prazosin are 100.34% and Polythiazide is 100.32% respectively. Prazosin and Polythiazide are more sensitive towards acidic, basic and oxidative degradation condition.[11]

2.LC Analysis of prazosin in API, Dosage form & serum: Application to drug – metal interaction studies prazosin in active pharmaceutical ingredient, dosage formulation and human serum using mobile phase 75:25 v/v acetonitrile:water having pH 3.20 adjusted with glacial acetic acid. Mobile phase was pumped at a flow rate of 1.5 mL min−1 using gradient elution through prepacked Nuclosil, C18 (250×4.6 mm,) column. UV detection was performed at 250 nm. Calibration curve was linear in concentration range 1.0-10 µg mL−1 with

correlation coefficient 0.9999, and lower limits of detection and quantitation as 3.3 and 2.2 ng mL−1 and 9.8 and 6.1 ng mL−1 in raw material and serum respectively. Recovery was found to be in the range 99-100% and precision less than 1%.[12]

3. the Validated HPLC method for determination of Prazosin, terazosin, and doxazosin in presence of degradation products Resolution of drugs from degradation products was obtained using a reversed-phase C-18 column using water/acetonitrile/methanol/glacial acetic acid/diethylamine (25:35:40:1:0.017) as mobile phase for prazosin and terazosin and acetonitrile/water/glacial acetic acid/diethylamine (65:35:1:0.02) for doxazosin. The detection was done at 254 nm.[15]

LC-MS/MS

1. To develop a rapid, sensitive, and high-throughput liquid chromatography-tandem mass spectrometry (LC-MS/MS) method for prazosin quantification in human plasma, validate its application in bioequivalence studies, and investigate sex-specific pharmacokinetic differences in a Chinese population. Plasma samples were processed by protein precipitation with methanol and analyzed using a Waters ACQUITY UPLC® HSS T3 column. Prazosin-d8 was used as an isotopic internal standard (IS) to enhance quantification accuracy. Chromatographic separation was performed with methanol (A) and 0.1% formic acid in water (B) as the mobile phases, using gradient elution at 0.35 mL/min. Quantification was achieved using positive ionization mode with multiple reaction monitoring (MRM) transitions of m/z 384.2→95.0 for prazosin and m/z 392.2→95.0 for IS.

2. Development and Validation of the LC-MS/MSin Human Plasma A simple, fast and sensitive LC-MS/MS method was developed to quantify terazosin in human plasma. The mobile phase consisted of acetonitrile-0.1% (v/v) formic acid (70:30, v/v). Prazosin was used as internal standard (IS). As deproteinization agent, acetonitrile produced a clean sample. A higher response intensity with more symmetrical peak was obtained using Agilent Poroshell 120 EC-C18 – Fast LC column (100 × 2.1mmID, 2.7 µm) compared with Kinetex XB-C18 (100 × 2.1 mm, 2.6 µm) column. The response of terazosin and IS were approximately two times in citrate phosphate dextrose (CPD) plasma compared with dipotassium ethylenediaminetetraacetic acid (K_2EDTA) plasma. Plasma calibration curve was linear from 1.0 to 100.0 ng/mL, with coefficient of determination $r^2 \geq 0.99$. The within-run and between-run precision values (CV, %) were <5.2% and <7.8%, while accuracy values were 102.8–112.7% and 103.4–112.2%. The extended run accuracy was 98.6–102.8% and precision (CV, %) 4.3–10.4%. The recovery of analyte was >98% and IS >94%. Terazosin in plasma kept at benchtop was stable for 24 h, in autosampler tray for 48 h, in instrumentation room for 48 h, for 7 freeze-thaw cycles and in freezer for 140 days. Terazosin and IS stock standard solutions were stable for 140 days at room temperature and in the chiller. The high throughput method was successfully utilized to measure 935 samples in a bioequivalence study of terazosin.

VARIOUS ANALYTICAL METHOD DEVELOPMENTS OF PRAZOSINHCl

UV Spectroscopy Methods

METHODS	MOBILE PHASE	WAVELENGTH
UV Spectrophotometric method development and validation of Prazosin HCl in bulk & tablet dosage form	0.01N HCl	246nm
Analytical method development & validation of Prazosin by UV-VIS Spectrophotometry	Phosphate buffer pH 7.4	257nm
Development and validation of UV Spectrophotometric for Prazosin	Phosphate buffer pH 6	247nm
UV-VIS Spectrophotometric method for Prazosin HCl tablets	Methanol	246nm
Spectrophotometric method development and validation of Prazosin	Methanol	2nm

HPLC METHODS

Methods	Mobile Phase	Flow Rate	Wavelength	Retention Time (RT)
Development and validation of RP-HPLC for Prazosin and Polythiazide	ACN and Potassium dihydrogen orthophosphate buffer (50:50,v/v)	1ml/min	265nm	2.989 & 2.134
LC Analysis of Prazosin in API, Dosage form & Serum: Metal interaction studies	ACN and water pH 3.20 with glacial acetic acid (75:25)	1.5 ml/min	250nm	10 mins
HPLC Method for Prazosin, terazosin, and doxazosin of degradation products	Water/ACN/ methanol/glacial acetic acid/ diethyl amine (25:35:40:1:0.0017)	----	254nm	------

RESULTS AND DISCUSSION

The review of published analytical methods for prazosin hydrochloride indicates that UV spectrophotometric and HPLC techniques are the most commonly used methods for its quantitative determination in bulk drugs and pharmaceutical formulations. UV methods are simple, rapid, and cost-effective, providing acceptable accuracy and precision for routine quality control. However, their selectivity may be limited in the presence of impurities and degradation products.

HPLC and RP-HPLC methods offer superior sensitivity, specificity, and reproducibility, making them the preferred choice for stability studies and quality assurance. Several validated methods demonstrated excellent linearity, accuracy, and robustness, enabling reliable estimation of prazosin in complex matrices. Recent advances in analytical science have also introduced green and chemometric-assisted techniques, which reduce solvent consumption while maintaining analytical performance.

Conclusion for Prazosin Hydrochloride

Prazosin hydrochloride is a selective α_1-adrenergic receptor antagonist widely used in the management of hypertension, benign prostatic hyperplasia, and certain trauma-related disorders such as post-traumatic stress disorder (PTSD). Owing to its well-established pharmacological profile, therapeutic effectiveness, and favorable safety characteristics, prazosin remains an important drug in clinical practice. Various analytical techniques, including HPLC, UPLC, UV–Visible spectrophotometry, HPTLC, and LC–MS methods, have been developed and validated for its identification, quantification, and quality control in pharmaceutical formulations and biological matrices. Continuous advancements in analytical methodologies have enhanced the sensitivity, accuracy, precision, and efficiency of prazosin analysis. Therefore, the development and validation of robust analytical methods are essential to ensure the quality, safety, and efficacy of prazosin hydrochloride in pharmaceutical products and support ongoing research and regulatory requirements.

AUTHORS CONTRIBUTIONS: All the authors have contributed equally.

CONFLICT OF INTERESTS: Declared note.

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