UV Spectrophotometric method development and validation of Prazosin HCl in bulk and tablet dosage form

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***Abstract*—A simple, precise, accurate and an inexpensive 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. 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. The validation parameters' results showed that the proposed approach was judged to be appropriate, sensitive, reproducible, accurate, and exact. Therefore, this method proves to be beneficial for regular quality control assessments of Prazosin HCl in both active pharmaceutical ingredients and tablet formulations.**

***Index Terms*—Prazosin HCl,tablet dosage form, uv-spectrophotometric, Validationetc.**

I. INTRODUCTION

Piperazine, 1–(4–amino–6,7–dimethoxy–2–quinazolinyl)–4–(2–furanyl) mono-hydrochloride (carbonyl) is the chemical name for Prazosin HCl (Figure 1)[1]. 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 [2,3].

This drug is frequently used to treat circulatory failure brought on by scorpion stings, hypertension, and refractory pulmonary edema[4]. 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 [5].

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[6] However, many of these conventional methods are time-intensive, as they are based on visual range spectroscopy[7]. 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).

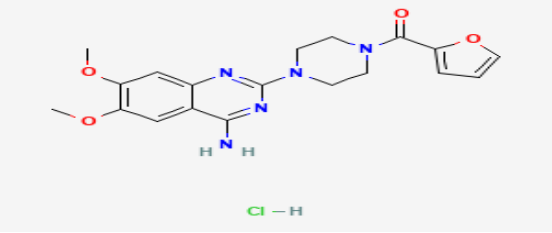

Figure 1 structure of Prazosin HCl

II.. MATERIAL AND METHODS

A. Chemical and reagents

Pharmaceutical grade Prazosin HCl was provided by Synthokem Labs pvt. Ltd., Telangana, India. Prazopress xl 5 mg tablet was purchased from local

vendor with The expiration date is at least 2 years at the time of study. chemicals were at analytical level**.**

B. Instrumentation

Electronic balance (contech CA-221), pH meter (equip-tronics, model no.EQ-615) with magnetic stirrer (equiptronics model EQ-770), UV Spectrophotometer (Shimadzu UV-1800)with 10 mm path length which was used in these study. Distillation unit (dolphin) were also used as deionizer to make distillation of water.

C. Preparation of Solvent

Preaparation of 0.01N HCl: 0.085 mL of HCl dissolved in 1000 mL of distilled water.

80 ml of 0.01N HCl and 20 mL of methanol solvent mixture was prepared and stirred which was used as solvent for this whole study.

D. Preparation of standard stock solution

Prazosin HCl (10 mg) was dissolved in 10 ml of solvent to create a standard stock solution (1000 µg/mL). One milliliter of 1000 µg/mL was then pipetted out and diluted with 10 milliliters of solvent to yield 100 µg/mL conc.

E. Preparation of solutions for calibration curve

From 100 µg/mL, appropriate volumes of solutions pipetted out and diluted upto 10 mL to get conc. of 2-10 µg/mL.

F. Determination of λ_{max}

The λ_{max} was determined by scanning a 10 µg/mL solution of Prazosin HCl within the spectrum range of 200-400 nm individually.The λmax was identified to be 246 nm used for further validation.

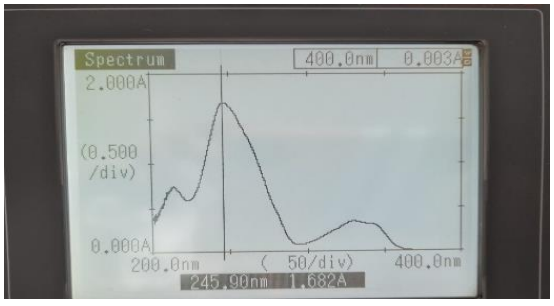

Figure 2 λ_{max} of Prazosin HCl

G. Preparation for solution of tablet powder

Weight equivalent to 10 mg of tablet powder was dissolved and diluted with solvent. From above solution specified volume pipetted out and diluted up to 10mL.Then 1 mL was pipette out from 1000 µg/mL and diluted to 10 mL with solvent to achieve the concentration 100 µg/mL.

H. Preparation of solution for tablet assay

From the above tablet solution powder, specified (0.6mL) volume was pipetted out and diluted to 10 mL to achieve concentration of 6 µg/mL and analyzed for UV spectroscopy.

J. Method validation

Method validation was performed according to ICH Q2 (R1) guidelines.

III. RESULTS AND DISCUSSION

1. Method development and optimization

The current study outlines the use of the absorption ratio technique to quantify Prazosin HCl in both bulk and tablet forms. This method was validated for parameters including linearity, accuracy, precision, detection limit (LOD), and quantitation limit (LOQ).

2. Validation:

2.1 *Linearity:* A calibration curve was established for Prazosin HCl in the concentration range of 2-10 µg/mL, using a maximum wavelength (λmax) of 246 nm. The results indicated a linear relationship for Prazosin HCl within the 2-10 µg/mL concentration range, with a regression coefficient of 0.9965 based on the absorbance ratio method. There was a strong correlation observed between concentration and absorbance.

conc. (µg/ml)	Abs
2	0.319
4	0.725
6	1.011
8	1.398
10	1.682

Table 1 calibration curve of Prazosin HCl

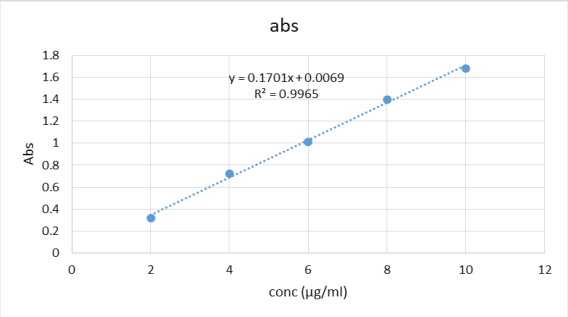

Figure 3calibration curve of Prazosin HCl

Parameters	Method values
Wavelength detection	246 nm
Beer's Law	2-10 µg/mL
Correlation coefficient	0.9965
Regression Coefficient	y= 0.1701x + 0.0069
Slope	0.17005
Intercept	0.0069

Table 2 optimized parameters of Prazosin HCl

2.2 Precision: For precision assessment, concentration 8 µg/mL was used to analyze in 6 times at 246 nm over a short interval of time.

Batch	absorbance	% Precession
P1	1.398	102.22
P2	1.397	102.15
P3	1.396	102.07
P4	1.395	102.00
P5	1.397	102.15
P6	1.396	102.07

Table 3 Results of % precision

2.3 Range: Range was fixed for Prazosin HCl (2-10 µg/mL).

2.4 Accuracy:

Preparation of standard solution (Std_{50})

From the 100 µg/mLconcentration Solution specified volume (5mL) was pipetted out and diluted to 10mL to achieve the 50 µg/mLconcentration Solution.

Preparation of Test solution (Tab_{50})

From the 100 µg/mLconcentration of tablet powder solution specified volume (5mL) was pipetted out and diluted to 10mL to achieve the 50 µg/mLconcentration. For accuracy, percentage recovery of Prazosin HCl was determined. This involved adding the analyte at concentration levels of 80%, 100%, 120%.

Recovery level (%)	Tab.$_{50}$ sol^{n} (mL)	Std.$_{50}$ sol^{n} (mL)	Amt. Recovered (µg/mL)	% recovery
0	1	0		
80	1	0.8	3.60	98 %
100	1	1	4.6	102%
120	1	1.2	5.60	103%

Table 4 Results of Accuracy

2.5 Detection limit: The detection limit is the minimum quantity of analyte in a sample that can be identified. It was calculated by following formula,

$LOD = 3.3 \times \sigma/S$

Were,

where σ represents the response's standard deviation.

S is the relevant calibration curve's slope.

It was discovered that the LOQ was 5.04 µg/mL.

2.6 Quantitation limit: The Quantitation limit is the minimum concentration of analyte that can be measured. It was computed using the following formula: $10 \times \sigma /S$ is the LOQ. The response's standard deviation is represented by σ. For the corresponding calibration curve, S is its slope. It was discovered that the LOQ was 5.04 µg/mL.

2.7 Assay

From *H.*,

Tablet Solution used	absorbance	Concentration (in µg/mL)	% purity
6 µg/mL	0.993	5.79	98%

Table 5 Results of assay

% Purity = concentration of test solution/ concentration of standard × 100

5.79/5.90 × 100 = 98.13 %

IV. CONCLUSION

For the purpose of determining as well as measuring Prazosin HCl, a rapid and safe UV spectrophotometric technique was created. The technique was also verified to meet ICH requirements for linearity, precision, accuracy, detection limit, and quantitation limit. Prazosin HCl in bulk and tablet dosage form can

be routinely analyzed for quality control using the current UV spectrophotometric method because it is linear, accurate, precise, and time-efficient.

V. ACKNOWLEDGEMENT

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