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Development And Validation Of A Novel And Simple Method To Determine Prazosin Hydrochloride By UV Spectrophotometry

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Abstract:

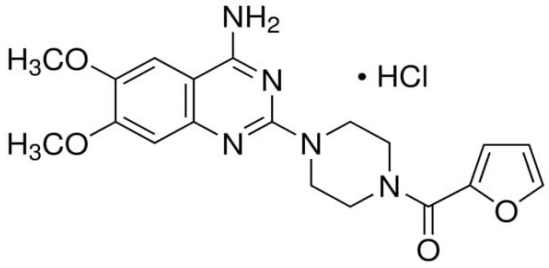
For the purpose of quantifying prazosin in active pharmaceutical components and tablet dose formulation, an affordable, straightforward, accurate, precise, and versatile UV spectrophotometric approach based on absorption ratio has been developed and verified in accordance with ICH requirements. In the current investigation, prazosin was estimated using the absorbance values at 243 nm. The analyses findings for linearity, accuracy, precision, LOD, and LOQ have all been statistically confirmed. With a correlation coefficient of 0.9988, the procedure was shown to be linear in the concentration range of 1–5 g/ml. The results for the validation parameters also showed that the suggested approach was determined to be appropriate, sensitive, repeatable, accurate, and exact. As a result, this technique is helpful for routine quality control analysis to estimate prazosin in pharmaceutical.

Keywords: Prazosin hydrochloride, Development, methanol, UV-Visible Spectrophotometric method, Validation

Introduction:

Anxiety, panic disorder, and high blood pressure are treated with prazosin hydrochloride (PRZ). Within the quinazoline family, PRZ is an oral antihypertensive medication1 and a strong vasodilator2 that may also be useful in the treatment of heart failure. 3. The selective α blocker in prostatic hyperplasia relaxes smooth muscle, increases urine flow rate, and alleviates obstructive symptoms. It is 1-(4-amino-6,7, -dimethoxy-2-quinazolinyl)-4-(2-furanyl carbonyl) piperazine monohydrochloride chemically, and it is a medication used to treat hypertension. There have been several reports on spectrophotometric techniques for determining prazosin in biological materials and pharmacological dose forms. However, the majority of the techniques fall under the category of visible range spectroscopy and are therefore labour-intensive. As a result, a straightforward, quick, accurate, and sensitive UV spectroscopy technique was created.

Fig.No.1 Structure of Prazosin Hydrochloride



Material: A complimentary sample of prazosin hydrochloride was provided by Synthokem Labs Private Limited, Unit II, Pashamylaram, Telangana, India. We bought 5 mg tablets of prazosin hydrochloride from the local market. All of the chemicals and reagents used were analytical grade.

Instrument: Double beam UV Spectrophotometer (Systronics-2201) and Weighing balance.

Chemicals: Dist. water, methanol, Prazosin hydrochloride

Method Development: Solvent selection: The choice of solvent was made after solubility testing in a 30:70 ratio of methanol and distilled water showed a greater absorbance value at λmax. Methanol and water were chosen as the solvent for additional research.

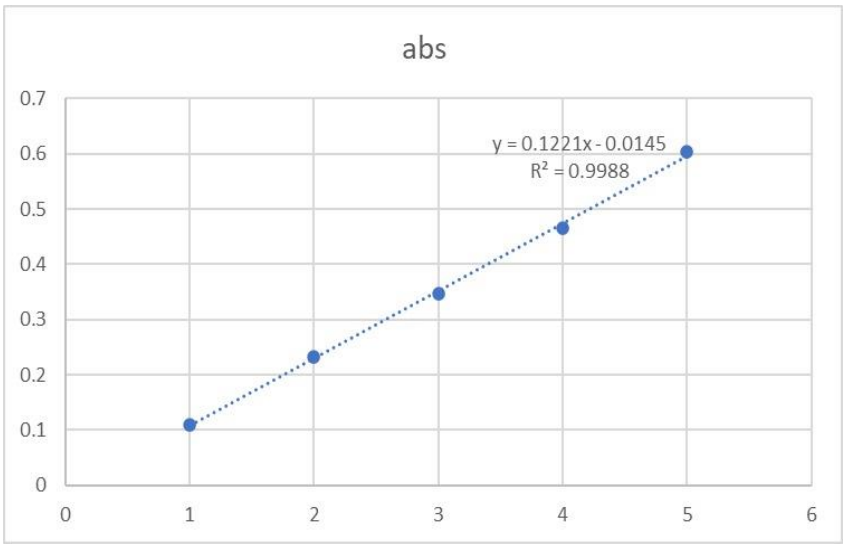
Fig.No.2 λ max of Prazosin hydrochloride

Standard stock solution preparation: Accurately weigh out 10 mg of prazosin hydrochloride and dissolve it in a 100-mL volumetric flask with methanol and distilled water (30:70). Use methanol and distilled water (30:70) (concentration 100µg/ml) to maintain the volume to the required standard. Pipette 5 ml of the solution and transfer it to a 50 ml volumetric flask. Use methanol: water (30:70) (concentration 10 µg/ml) to make up the volume to the mark. The wavelength corresponding to the greatest absorbance at 243 nm was found by scanning the sample with a UV-VIS spectrophotometer between 200 and 400 nm.

Preparation of Working standard solution: Assemble concentrations between 1 µg and 5 µg per millilitre. 1 ml of the standard stock solution above should be pipetted, transferred to a 10 ml volumetric flask, and make up the volume up to the mark with 30:70 methanol: water, have a concentration of 1 µg/ml. Pipette 2, 3, 4, and 5 ml from the standard stock solution for higher concentrations of 2, 3, 4, and 5 µg/ml. Transfer the mixture to a 10-ml volumetric flask and top it off with methanol: water (30:70).

Calibration curve: A concentration range of 1–5 µg/ml was used for the calibration curve, and six distinct concentrations were generated and measured at 243 nm. There was a straight line on the generated graph.

Fig No. 3: Calibration curve of Prazosin Hydrochloride



Method Validation: Method Validation was performed according to ICH [Q2 (R1)] guidelines.

Linearity: Using the stock solution (10µg/ml) as a blank, different aliquots ranging in size from 1 to 5µg/ml were produced and scanned at 243 nm in a UV-VIS spectrophotometer. The results showed a regression coefficient of 0.9988 and absorbance within the allowable range.

Table 1: Optimization parameter of Prazosin hydrochloride

Parameters	Method values
Wavelength detection	243
Beers law	1 µg/ml -5 µg/ml
Correlation coefficient	0.998
Regression coefficient	Y=0.0122x-0.0145
Slope	0.0122
Intercept	0.0145

1.Precision: For precision assessment, conc. of 5µg/ml was used to perform inter-day and intra-day precision. Results obtained fell within the acceptable limit, demonstrating a relative standard deviation (RSD) of less than 1%.

Table 2: Intra-Day Precision

Sr. No	Concentration	Absorbance
1	5 µg/ml	0.466
2		0.459
3		0.461
4		0.466
5		0.466
6		0.463
	Mean	0.4635
	SD	0.002754
	%RSD	0.59%

Table 3: Inter-Day Precision

Sr.No.	Concentration	Absorbance (1st Day)	Absorbance (2nd Day)
1	5 µg/ml	0.461	0.466
2		0.463	0.464
3		0.459	0.461
4		0.461	0.466
5		0.458	0.463
6		0.460	0.465
	Mean	0.460333	0.464167
	SD	0.001599	0.001772
	%RSD	0.34%	0.38%

2. Range: Range was fixed for prazosin hydrochloride (1-5µg/ml).

3. Accuracy: For Accuracy, percentage recovery of prazosin hydrochloride was determined. This involved adding the analyte at concentration levels of 80%, 100%, and 120%.

Table 4: Result of accuracy

Recovery level in %	Concentration of sample (µg/ml)	Concentration of drug (µg/ml)	Amount recovered (µg/ml)	% Recovery
80%	1	0.8	1.844	102.44%
100%	1	1	2.008	104.4%
120%	1	1.2	2.254	102.45%

4. Detection Limit: Detection Limit is the lowest amount of analyte in sample that can be detected. It was calculated by following formula.

Detection limit = 3.3*σ/S Where, σ and S are the standard deviation of the response and the slope of calibration curve. The detection limit was found to be 0.744µg/ml.

5. Quantitation Limit: Quantitation limit is the lowest amount of analyte in sample that can be quantified. It was calculated by following formula.

Quantitation limit = 10*σ/S Where, σ and S are the standard deviation of the response and the slope of calibration curve. The quantitation limit was found to be 2.25µg/ml.

6. Robustness: Robustness shows negligible impact of the absorption level of Prazosin hydrochloride solution in ethanol at different wavelength (±2nm).

Table 5: Result of Robustness

Sr. No	Absorbance at 241	Absorbance at 245
1	0.461	0.475
2	0.463	0.471
3	0.465	0.465
SD	0.001633	0.470
%RSD	0.35	0.87%

7. Assay: Assay of sample solution was also determined.

Table 6: Result of Assay

Formulation	Concentration (µg/ml)	Obtained amount (µg/ml)	% purity
Prazosin Hydrochloride 5mg tablets	1.5	1.557	103.82%

Results and discussion: With favourable drug recoveries and %RSD values of both intra-day and inter-day experiments less than 1%, the method showed accuracy, simplicity, precision, and repeatability. The technique demonstrated robustness with %RSD values less than 2%, and the detection and quantitation limits were determined to be (0.744, 2.25). Specificity was verified, and Table No. 7 presents validation respectively.

Table 7: Validation Parameters

Sr. No	Parameters	Result
1	Linearity indicated by correlation coefficient	0.998
2	Linear Regression Equation	0.0122x-0.0145
3	Range	1 µg/ml -5 µg/ml
4	Intraday Precision	0.59%
5	Interday Precision	0.36%
6	Detection limit	0.744µg/ml
7	Quantitation limit	2.25µg/ml
8	Recovery indicated by%	95-105%
9	Robustness indicated by %RSD	0.61%

Conclusion: The created approach met particular requirements designed for specificity, precision, linearity, accuracy, and robustness, and it conformed to ICH [Q2(R1)] recommendations. To sum up, this analytical approach is thought to be suitable for the goal it is intended to achieve.

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