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Research Article

Development and Validation of UV Spectroscopic Method for Estimation of Propranolol in Bulk and Tablet Dosage Form

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ABSTRACT

Background: Propranolol is a widely used non-selective beta-blocker prescribed for hypertension, arrhythmias, and anxiety -related conditions. Simple, robust, and cost-effective analytical methods are essential for its routine quality control in pharmaceutical formulations. **Materials and Methods:** A UV Spectroscopic method was developed and validated in accordance with ICH Q2 (R1) guidelines for the estimation of Propranolol. The method was validated for parameters including linearity, accuracy, precision, robustness, ruggedness, Limit of Detection (LOD), Limit of Quantification (LOQ), Assay and solution stability. The absorbance was measured using a suitable wavelength and standard and test solutions were prepared accordingly. **Results:** The method showed linearity in the concentration range of 1-8 µg/mL with a correlation coefficient (R2) of 0.999. Accuracy was within the acceptable range, with recovery values between 97.34% and 100.1%. Precision studies yielded % RSD values of less than 2%, indicating good repeatability and intermediate precision. This method was robust and rugged under small deliberate variations. The LOD and LOQ were found to be below 1 µg/mL, confirming high sensitivity. The assay result was 100.62% and the standard stock solution was stable for 24 hr at room temperature. **Conclusion:** The validated UV Spectroscopic method is simple, accurate, precise, and cost-effective. It is suitable for routine analysis and quality control of Propranolol in bulk drug and pharmaceutical dosage forms.

Keywords: Propranolol, UV Spectroscopy, Method validation, ICH guidelines, Stability.

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INTRODUCTION

Propranolol hydrochloride, chemically known as (RS)-1-(isopropylamino)-3-(naphthalen-1-yloxy)propan-2-ol hydrochloride, is a non-selective beta-adrenergic receptor blocker. It is widely used in the treatment of hypertension, cardiac arrhythmias, angina pectoris, myocardial infarction, and migraine prophylaxis. The drug works by blocking β1 and β2 adrenergic receptors, reducing heart rate, cardiac output, and blood pressure.[1,2] This study aims to develop a simple, precise, and accurate UV spectrophotometric method for the estimation of propranolol hydrochloride in bulk and tablet dosage form. The method was validated in accordance with ICH Q2(R1) guidelines to assess its linearity, accuracy, precision, Limit of Detection (LOD), and Limit of Quantitation (LOQ).

Several UV spectrophotometric methods have been developed for the estimation of propranolol hydrochloride in bulk and pharmaceutical formulations.[3,4] Simultaneous estimations with other drugs have been successfully demonstrated in previous studies,[5,6] while a sensitive method employing MBTH as a chromogenic reagent was developed in an earlier investigation.[7] These studies highlight the reliability and versatility of UV spectrophotometry in propranolol analysis. The proposed method was found to be more sensitive compared to the previously reported methods. These studies.[8-10] were referred to as foundational literature to understand UV spectrophotometric principles and method development approaches, which guided the progression of the present work.

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MATERIALS AND METHODS

Instruments

A LABINDIA UV-Visible spectrophotometer equipped with 1 cm quartz cuvettes was used for measuring absorbance. Shimadzu electronic balance (Model AX-200) was employed for precise weighing of samples. An ultrasonicator (Citizen) was utilized to ensure uniform dissolution of the drug.

Materials

Propranolol hydrochloride API of analytical grade was used for method development. 0.1 N hydrochloric acid served as the solvent for the preparation of standard and test solutions.

Solvent selection for analysis

A number of trials were done to find out the ideal solvent system for dissolving the drug. The solvents such as distilled water and 0.1N Hydrochloric acid (HCl) were tried based on the solubility of the drug. Finally, 0.1 N Hydrochloric acid was selected as a solvent for method development.

Wavelength determination

The wavelength for analysis of Propranolol was selected from the UV-spectrum. To find out the λ_{max} of three replicates 4 µg/mL concentration of Propranolol was prepared, and it was scanned in the UV range between 200-400 nm. The absorbance maxima (λ_{max}) were found at 221 nm against 0.1N HCl. Figure 1 is wavelength maxima Propranolol for 4 µg/mL.

Preparation of standard stock solution

Weighed and transferred accurately about 20mg of Propranolol into a 100 mL clean dry volumetric flask, then dissolved and made up this volume with 0.1 N HCl and finally sonicated for 5 min and marked it as Stock-1 (200 µg/mL).

Solution prepared for calibration curve

Aliquots (0.05 mL, 0.1 mL, 0.15 mL, 0.2 mL, 0.25 mL, 0.3mL, 0.35 mL and 0.4 mL) of prepared standard solution were transferred into series of 10 mL volumetric flasks and diluted by 0.1 N HCl to give the concentration range of 1-8 µg/mL. The above solutions were scanned over the range of 200 nm to 400 nm against reagent blank. The absorbance of each solution at 221nm was scanned against 0.1N HCl as blank. A calibration curve was prepared by plotting absorbance versus concentration.

RESULTS AND DISCUSSION

Linearity

Fresh aliquots were prepared from standard stock solutions ranging from 1-8 µg/mL and the absorbance values of each concentration were recorded at 221nm for this method using 0.1N HCl as blank. The drug shows linearity between 1-8 µg/mL for this method. Linearity results are displayed in Table 1. Figures 2 and 3 are calibration curve of propranolol and overlay of different concentrations for linearity, respectively.

Limit of Detection and Limit of Quantitation

Limit of Detection (LOD) and Limit of Quantitation (LOQ) values were used to describe the method sensitivity. It was calculated by taking the slope and standard deviation of response from calibration curve of analyte, which were for determining the linearity. It is done by using following formulas and results were found to be <1(Table 2) so the proposed method was sensitive.

LOQ and LOD were calculated as following:

$$LOD = 3.3 \times 0.00124/0.12643=0.032\ \mu g/mL$$

$$LOQ=10\times0.00124/0.12643=0.0988\ \mu g/mL$$

Precision

In intra-day study, concentration of replicates of drug was calculated on the same day two times. In inter-day study the concentration of drug was calculated on three successive days which expresses the laboratory variation in different days. In both intra and inter day precision study for the methods % RSD was calculated. Tables 3 and 4 are the results of intra-day and inter-day precision, respectively.

Accuracy

Recovery trials at three distinct API levels (50%, 100%, and 150%) were performed using the test sample addition method.

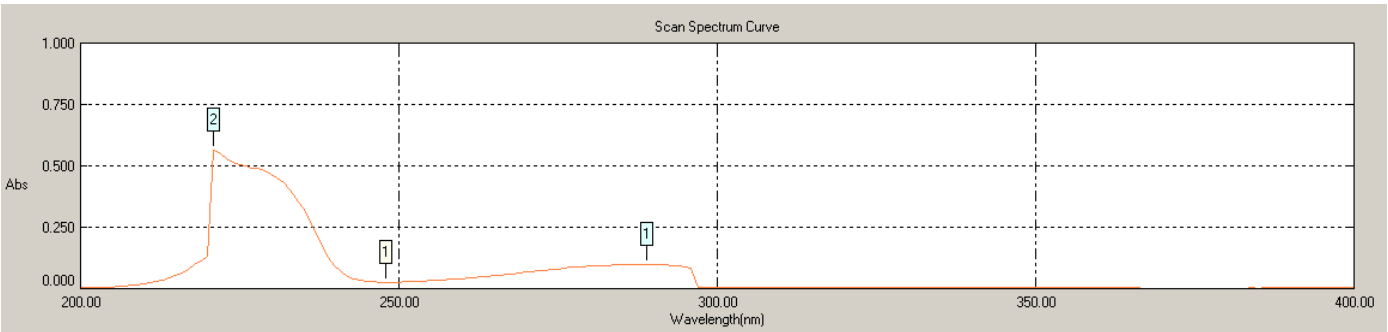

Figure 1: Wavelength maxima of Propranolol for 4 µg/mL.

Table 1: Linearity Results.

Concentration (µg/mL)	Absorbance (*n*=3)	SD	%RSD
1	0.161	0.0015	0.932
2	0.274	0.0045	1.642
3	0.402	0.001	0.2487
4	0.520	0.0015	0.288
5	0.655	0.01	1.5267
6	0.766	0.0015	0.195
7	0.904	0.004	0.442
8	1.033	0.005	0.048

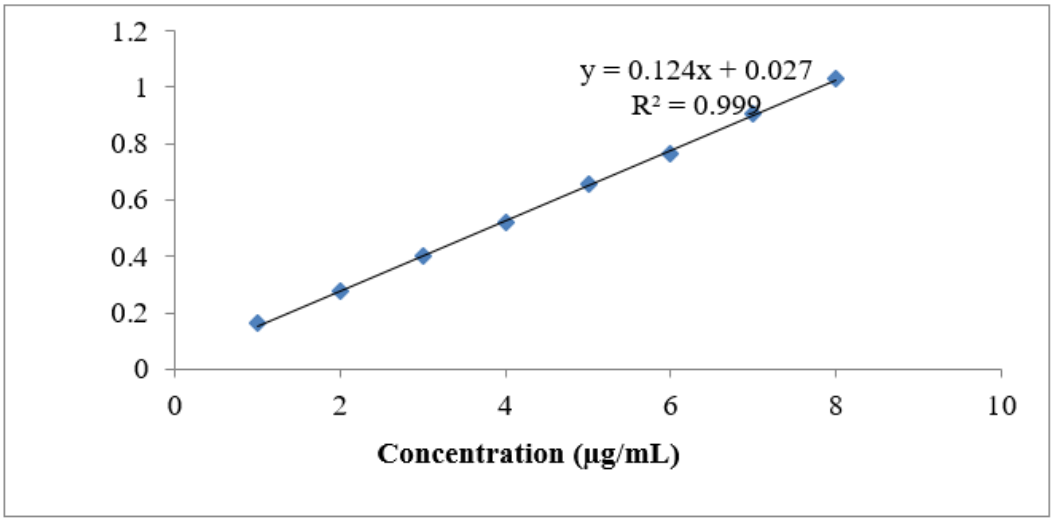

Figure 2: Calibration curve of Propranolol.

Table 2: LOD and LOQ Results.

API	LOD (µg/mL)	LOQ (µg/mL)
Propranolol	0.032	0.098

Accuracy is determined by calculating % recovery and mean % recovery. The mean % recovery was found to be in the range between 97.34-103.3%. Accuracy results are displayed in Table 5.

Robustness

To establish that the robustness of the method, six replicates of working standard solution were prepared and absorbance was checked at variable method condition like using different wavelengths (max±1 nm). The % RSD values were found to be < 2 and it indicated that the developed method was robust.

Ruggedness

Six replicates of the working standard solution were used to examine analyst to analyst variation for ruggedness studies. The % RSD values were found to be < 2. Ruggedness results are displayed in Table 6.

Table 3: Results of intra-day precision.

Intra-day precision		
Concentration	Morning	Evening
4 µg/mL	0.499	0.509
4 µg/mL	0.498	0.509
4 µg/mL	0.504	0.509
4 µg/mL	0.513	0.503
4 µg/mL	0.514	0.513
4 µg/mL	0.515	0.513
Average	0.507	0.509
SD	0.008	0.004
% RSD	1.57	0.78

Assay

15 tablets weigh accurately lexis 10 mg, the average weight was determined the Tablets were then broken down into fine powder. Accurately weighing 20 mg of the equivalent powder, it was then put into a 100 mL volumetric flask, and the final volume was made up with 0.1N HCl. 1 mL of this solution was pipette

Table 4: Results of inter-day precision.

Inter-day precision			
Concentration	**Day 1**	**Day 2**	**Day 3**
4 µg/mL	0.492	0.501	0.492
4 µg/mL	0.492	0.506	0.492
4 µg/mL	0.495	0.507	0.499
4 µg/mL	0.499	0.499	0.494
4 µg/mL	0.501	0.511	0.495
4 µg/mL	0.507	0.508	0.501
Average	0.498	0.505	0.500
SD	0.006	0.005	0.004
% RSD	1.20	0.99	0.80

Table 5: Results of accuracy.

% Level	Vol. of s standard added (200 µg/mL)	Volume of Test added (4 µg/mL)	Final conc. (µg/mL)	Absorbance	X	Amount Found. (x-test)	% Recovery	Mean % Recovery
50%	0.2	5 mL	6	0.781	6.063	(6.063-2) =4.063	101.57	101.5
50%	0.2	5 mL	6	0.757	5.873	(5.873-2) =3.873	96.825	
50%	0.2	5 mL	6	0.805	6.253	(6.253-2) =4.253	106.32	
100%	0.3	5 mL	8	1.061	8.285	(8.285-2) =6.285	104.75	103.3
100%	0.3	5 mL	8	1.049	8.190	(8.190-2) =6.190	103.17	
100%	0.3	5 mL	8	1.040	8.119	(8.119-2) =6.119	101.98	
150%	0.4	5 mL	10	1.253	9.809	(9.809-2) =7.809	97.61	97.34
150%	0.4	5 mL	10	1.252	9.801	(9.801-2) =7.801	97.51	
150%	0.4	5 mL	10	1.246	9.753	(9.753-2) =7.753	96.91	

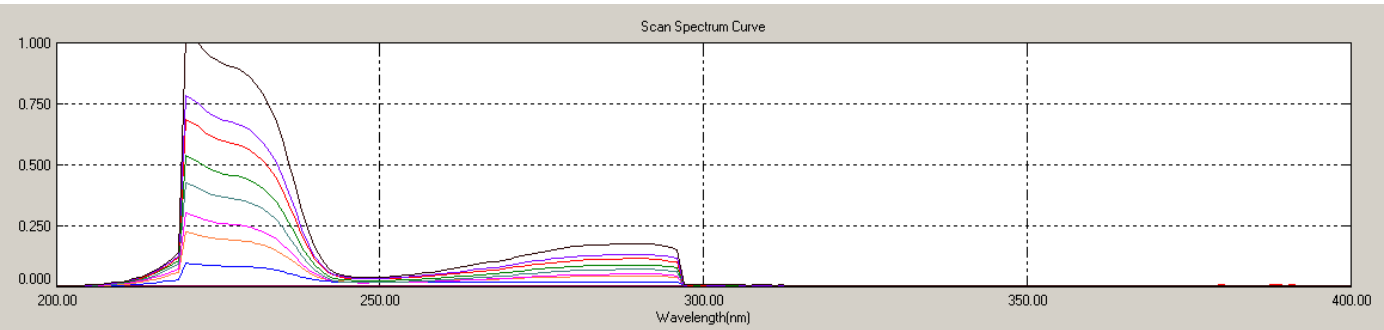

Figure 3: Overlay of different concentrations for linearity.

Table 6: Results of ruggedness.

Analyst-1 (*n*=3)		Analyst-2 (*n*=3)	
Concentration (µg/mL)	Absorbance (*n*=3)	Concentration (µg/mL)	Absorbance (*n*=3)
4	0.528	4	0.483
4	0.522	4	0.485
4	0.526	4	0.491
4	0. 530	4	0.493
4	0.525	4	0.500
4	0.540	4	0.503
Average	0.529	Average	0.493
SD	0.006	SD	0.008
% RSD	1.13%	% RSD	1.62%

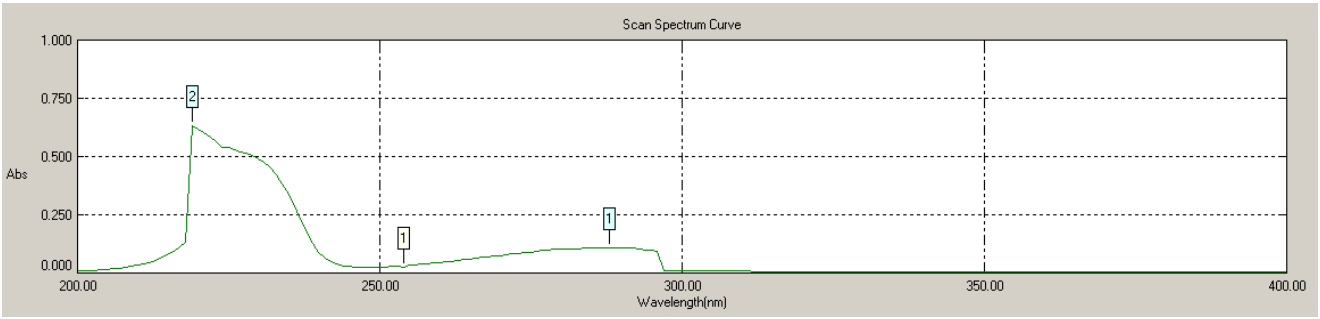

Figure 4: Assay Chromatogram of sample -1.

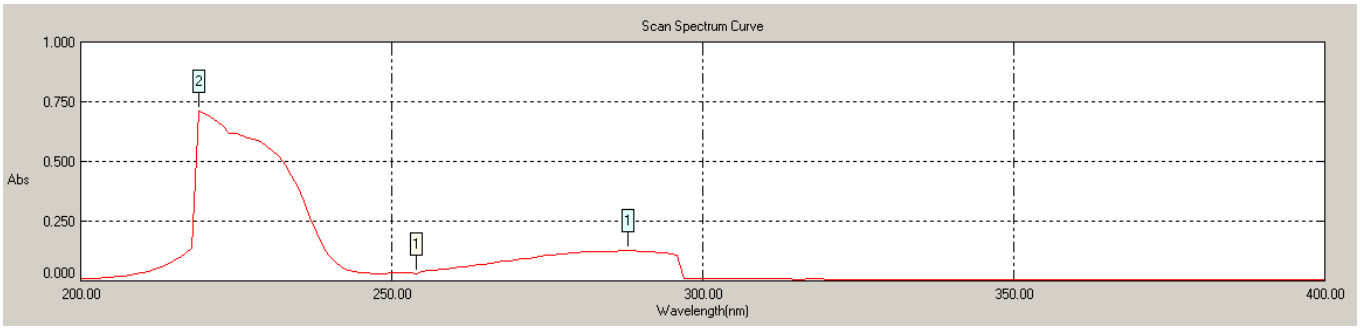

Figure 5: Assay Chromatogram of sample -2.

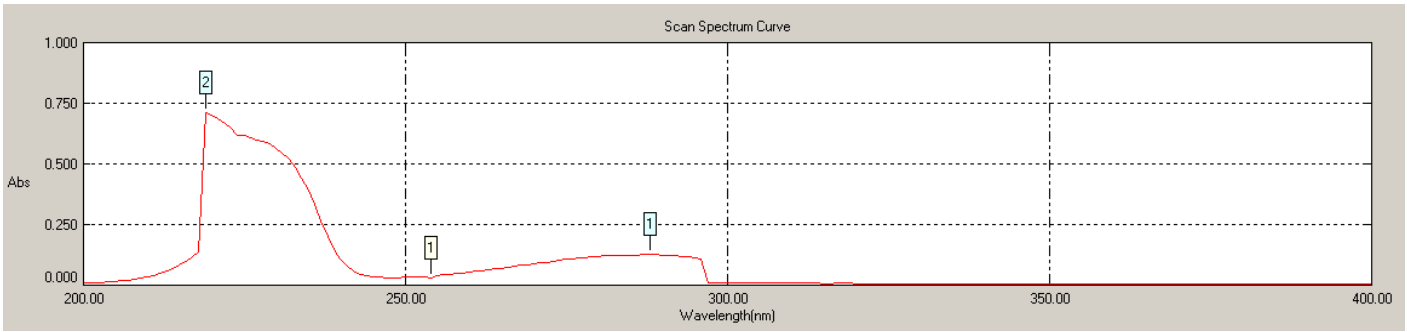

Figure 6: Assay Chromatogram of sample -3.

Table 7: Absorbance of standard and test solutions at selected concentrations for Propranolol assay.

Concentration (µg/mL)	Test absorbance	Standard absorbance
4	0.636	0.631
4	0.638	0.648
4	0.652	0.636
Average	0.642	0.638
SD	0.008718	0.009165
%RSD	1.36%	1.43%

Table 8: Assay results of marketed formulation.

Formulation	Propranolol
Brand name	Inderal LA
Label claim	10 mg/tablet
%Mean assay	100.62
Amount found (mg/tablet)	10.062

out into a 10 mL of volumetric flask and then diluted with 0.1 N HCl solutions to get the final concentration of 4 µg/mL. 0.2 mL of above solution was then further diluted to 10 mL. The resultant solution was determined by scanning in the UV region of 200-400 nm. Figures 4-6 are assay chromatograms. Tables 7 and 8 are results of assay.

Stability of standard solution

The standard solution was found to be stable for a period of 24 hr when stored at room temperature. No significant change was observed in absorbance values or spectral characteristics during this period, indicating that the solution remained chemically stable and suitable for use in analysis for up to 24 hr.

CONCLUSION

The validated UV spectroscopic method for Propranolol quantification is simple, accurate, precise, and cost-effective. It demonstrates excellent linearity (R^2=0.999) across 1-8 µg/mL, high accuracy (97.34-100.1%), and precision (%RSD < 2%), fully compliant with ICH Q2(R1). It also exhibits strong robustness and ruggedness, maintaining solution stability at room temperature for 24 hr. The assay result of 100.062% confirms its reliability for content uniformity testing. Crucially, the method shows enhanced sensitivity, with LOD and LOQ values below 1 µg/mL outperforming previously published UV methodologies. For instance, Kansa Noori *et al.*, reported LOD and LOQ values of 0.097 µg/mL and 0.29 µg/mL respectively, for a Propranolol HCl UV method in the 5-25 µg/mL range. This improvement highlights our method's superior capability for detecting and quantifying low concentrations, making it especially suitable for low-dose formulations and stringent quality-control environments. Overall, this method is not only efficient and robust, but also exceptionally sensitive, providing significant advantages for pharmaceutical industry and regulatory applications.

ACKNOWLEDGEMENT

The authors declare that there is no acknowledgement.

ABBREVIATIONS

API: Active Pharmaceutical Ingredient; **HCl:** Hydrochloric Acid; **λ_{max}:** Wavelength of Maximum Absorbance; **LOD:** Limit of Detection; **LOQ:** Limit of Quantitation; **RSD:** Relative Standard Deviation; **SD:** Standard Deviation; **UV:** Ultraviolet; **%RSD:** Percent Relative Standard Deviation; **ICH:** International Council for Harmonisation; **HPLC:** High Performance Liquid Chromatography (mentioned in comparison).

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

The study successfully established a validated UV spectroscopic method for the estimation of Propranolol in bulk and tablet dosage forms. The method proved to be simple, precise, accurate, and highly sensitive with excellent linearity (1-8 µg/mL) and low LOD/LOQ values. Its robustness, ruggedness, and stability make it suitable for routine quality control and regulatory applications in the pharmaceutical industry.

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