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ESTIMATION OF IMIDAPRIL HYDROCHLORIDE BY UV - VISIBLE SPECTROSCOPIC METHOD IN DIFFERENT SOLVENTS

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ABSTRACT

The objective of the project work was to developed and validated simple, accurate, rapid, precise, reproducible and cost effective spectrophotometric method for the quantitative estimation of Imidapril HCl in different solvents like 0.1N HCl, Distilled water and 0.1N NaOH in bulk based on measurement of absorption at maximum wavelength and validated as per ICH guidelines. Imidapril hydrochloride is a angiotensin-converting enzyme (ACE) inhibitor with IC50 of 2.6 nM, used for the treatment of hypertension. Imidapril HCl showed absorption maximum (λ_{max}) in different manner in different solvents like 0.1N Hydrochloric acid, Distilled Water and 0.1N Sodium Hydroxide Solution at 217 nm, 293 nm, and 236 nm respectively. The drug exhibited maximum wavelength (nm) in distilled water, 293 nm when compared with other solvents due to the effect of solvent and chromophoric group. Thus the conclusion was made that the proposed UV Spectrophotometric method were found to be simple, rapid, accurate, precise, linear and more economical method has been developed for the quantitative estimation of imidapril HCl in bulk. Hence, this method can be successfully and suitably acquired for routine quality control analysis of imidapril HC in bulk form.

KEYWORDS: Imidapril HCl, Method development, UV Spectrophotometer, Validation.

INTRODUCTION

Ultraviolet spectroscopy is concerned with the study of absorption of UV radiation which range from 200 to 400 nm. But compounds which are colorless absorb radiation in the UV region. [1] In both UV as well as visible spectroscopy, only the valence electrons absorb the energy, there by the molecule undergoes transition from ground state to excited state. This absorption is characteristic and depends on the mixture nature of electron present. [2] The intensity of absorption depends on the concentration and path length as given by beer-Lambert's law. According to the Beer's-Lambert's Law, absorbance is proportional to concentration, and Absorbance versus concentration plot is a straight line. [3]

The expression of Beer-Lambert law is-

$$\mathbf{A = \log (I_0/I) = ECl}$$

Where,

A = absorbance, I_0 = intensity of light incident upon sample cell

I = intensity of light leaving sample cell, C = molar concentration of solute

L = length of sample cell (cm.), E = molar absorptivity.

Fig.1: UV-VISIBLE double beam spectrophotometer.

The study makes an attempt to establish sensitive and accurate novel analytical method for Spectrophotometric estimation of Imidapril Hydrochloride in different solvents in bulk. UV-VISIBLE Spectrophotometer in different solvents like 0.1N Hydrochloric acid, Distilled Water and 0.1N Sodium hydroxide solution.[4] The method also validated for various analytical parameters according to ICH guidelines. To applied the proposed method for the analysis of drug in their bulk. Imidapril hydrochloride is a angiotensin-converting enzyme (ACE) inhibitor with IC50 of 2.6 nM, used for the treatment of hypertension.[8]

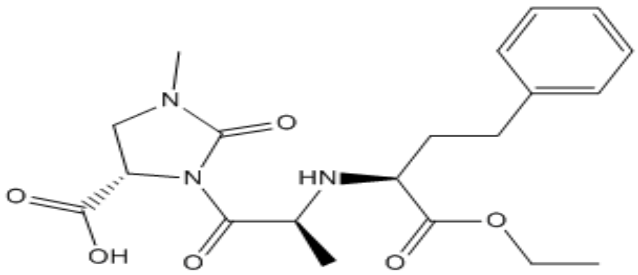

Fig. 2: Chemical structure of Imidapril hydrochloride.

MATERIALS AND METHODS

Instrument

Analytical Technologies double beam spectrophotometer with UV Probe software version 2 was used to develop the analytical method. The above instruments had automatic wavelength accuracy 0.1 nm and matched quartz cells with 1 cm cell path length, Ultra Sonicator and Weighing balance (Shimadzu, Japan) were used for this work.

Material

Imidapril hydrochloride was gifted from Aurabindo Pvt Ltd Hyderabad, India. The commercially available marketed tablets tindamax 500 mg, mankind, India Ltd. were obtained from the market. Hydrochloric acid, Ethanol, and sodium hydroxide was used as solvents were obtained from Amul Scientific, India. The Distilled water was used obtained from Water purification unit.

Method development

Preparation of Standard solution

A spectrum of the working standards was obtained by scanning from 200-400 nm against the solvent as blank to fix absorption maximum using double beam UV-Visible spectrophotometer. Here using various solvents like 0.1N Hydrochloric acid, Distilled Water and 0.1N Sodium hydroxide solution for the estimation of Imidapril hydrochloride. A Standard stock solution was prepared by accurately weighed 100 mg of Imidapril hydrochloride in 100 ml of volumetric flask and dissolved in 0.1N HCl to obtain a concentration 1 mg/1ml or 1000 µg/ml (Standard Stock I). Pipette out 10 ml of stock solution - I and make up to the volume 100 ml with 0.1N HCl to get desired concentration of 100 µg/ml (Stock II solution). From the stock –II solution prepared various concentrations; the same procedure repeated with other solvents like Distilled water and 0.1N Sodium hydroxide solutions.[7]

Selection of wavelength for analysis of Imidapril hydrochloride

Accurately measured 1.0 ml of standard stock II solution was transferred into 10 ml volumetric flask and diluted to 10 ml to give concentration of 10 µg/ml and it was used for initial spectral scan in the UV range of 200-400 nm to detect maximum wavelength and further dilutions for linearity were prepared from the stock solution by allegation method.[5]

Preparation of serial dilutions

The serial dilutions were prepared from the standard stock II solution to get a respective concentration of 2, 4, 6, and 8 up to 20 µg/ml.[6]

Method validation

The proposed method was validated for various parameters such as linearity and range, accuracy, precision, robustness, ruggedness, sensitivity and specificity according to ICH Q2 (R1) guideline and USP guidelines.[4]

Linearity and range

The linearity of an analytical procedure is its ability (within a given range) to obtain test result which are directly proportional to the concentration of an analyte in the sample. The range of an analytical procedure is the interval between the upper and lower concentration of an analyte in the sample for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity. The linearity of the analytical method was demonstrated over the concentration range investigated by triplicate analysis (n = 3) at a concentration range of 2-20 µg/ml. The absorbance obtained at respective concentration was recorded, and the graph is plotted as concentration (µg/ml) versus absorbance. The linear regression equation and the coefficient correlation were obtained from the UV probe software.[9]

Accuracy

The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. This is sometimes termed trueness. The accuracy of proposed method was determined on the basis of recovery study. Recovery study was carried out by spiking standard working solution to sample solution (formulation) at three different levels 80%, 100% and 120%. The final concentration of Imidapril HCl was determined at each levels of

the amount; three determinations were performed. The percentage recovery was calculated as mean ± standard deviation.[10]

Precision

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the homogeneous sample under the prescribed conditions. The precision of the method was demonstrated by intra-day and inter-day variation studies. In the intra-day precision study, three different solutions of same concentration were prepared and analysed in the same day (morning, noon and evening), whereas in the inter-day precision study, the solutions of same concentration were prepared and analysed, for three consecutive days, and the absorbance were recorded. All study was performed in triplicates. The result was indicated by calculating percentage RSD.[11]

Robustness

The robustness of an analytical procedure is a measure of its capacity remains unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.[12]

Ruggedness

The ruggedness is a degree of reproducibility of test result under verification of condition like a different analyst, different instruments and different days.[13]

RESULTS AND DISCUSSION

Selection of wavelength

It was concluded that the drug, Imidapril HCl showed absorption maximum (λ_{max}) in different manner in different solvents like 0.1N Hydrochloric acid, Distilled Water and 0.1N Sodium Hydroxide Solution at 217 nm, 293 nm, and 236 nm respectively. Therefore the observed λ_{max} values were used for further work to analyze the test samples. Among the three solvents 0.1N Hydrochloric acid showed greater absorbance, it was 1.099 at the concentration of 20 µg/ml, the maximum absorbance was 217 nm which is due to the effect of solvent like 0.1N Hydrochloric acid on Imidapril HCl when compared with other solvents like 0.1N Sodium hydroxide solution, and Distilled water. The lowest absorbance was 0.604 at the wavelength of 236 nm which is due to the effect of solvent like 0.1N Sodium hydroxide solution; the maximum absorbance was 293 nm in distilled water due to good solubility of drug in distilled

water. The drug of Imidapril HCl exhibited different wavelength and absorbance in different solvents because of the change of chromophoric groups; it is called as the effect of solvent on absorption maximum of Imidapril HCl.

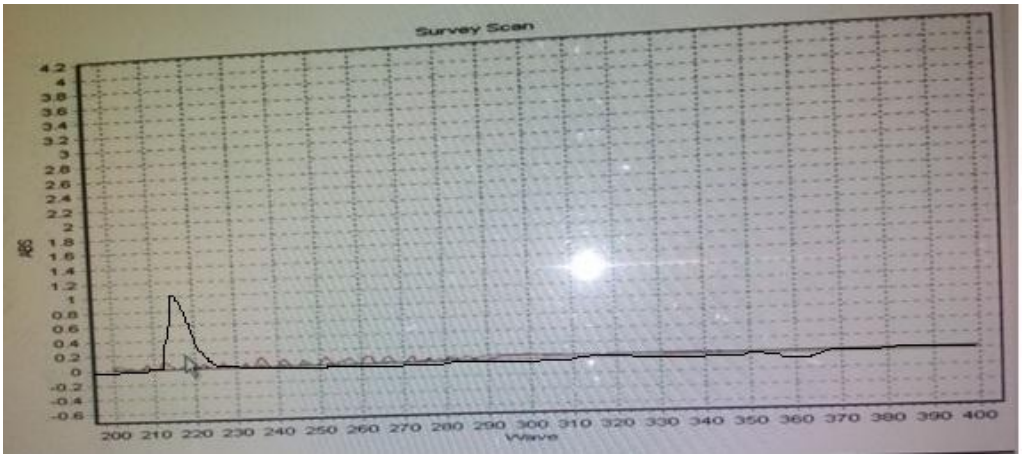

Fig.3: Absorption maximum (λ_{max}) of Imidapril HCl in pH 1.2 (0.1N HCl-217 nm).

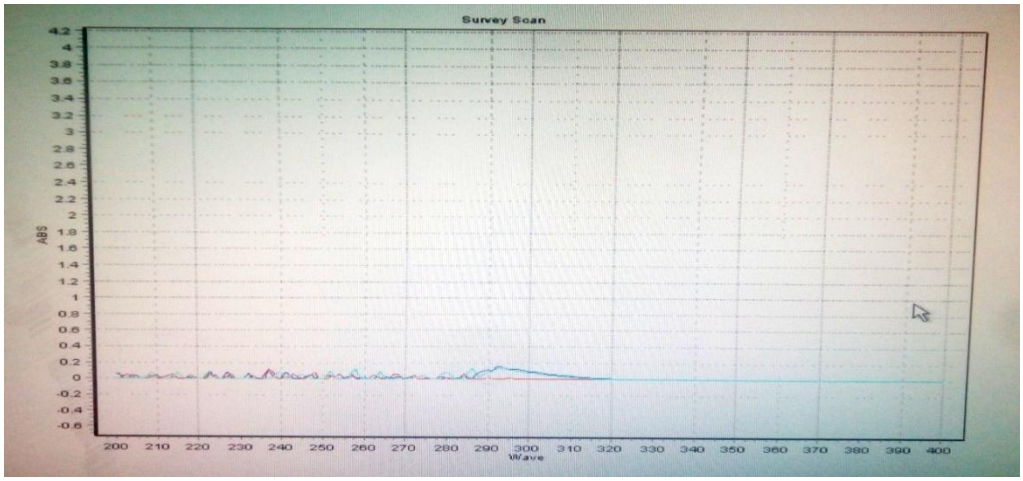

Fig.4: absorption maximum (λ_{max}) of Imidapril HCl in Distilled Water (293 nm).

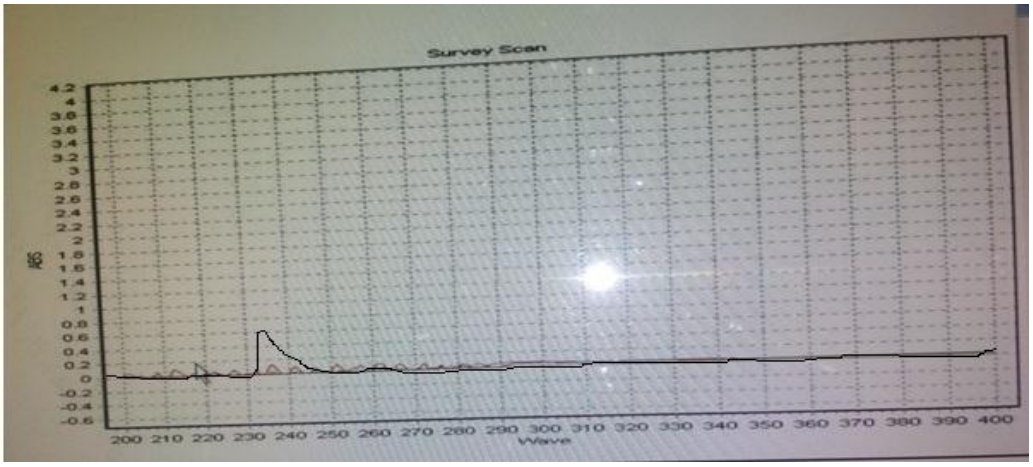

Fig.5: Absorption maximum (λ_{max}) of Imidapril HCl in 0.1N NaOH (236 nm).

Linearity and range

The linearity for the developed method was investigated by replicate analysis (n=3) at seven concentration levels (2-20 µg/ml) of reference standard Imidapril HCl. The absorbance obtained at respective concentration was recorded and graph was plotted shows good linear correlation coefficient from the UV probe software. The linearity was shown in table 1, 2, and 3 and fig. 6, 7 and 8.

Table.1: Standard calibration curve of Imidapril HCl in 0.1N HCl.

Flask No.	Volume of Stock-II (ml)	Volume made up to (ml)	Concentration (µg/ml)	Absorbance at 217 nm
1	0.2	10	2	0.149
2	0.4	10	4	0.261
3	0.6	10	6	0.373
4	0.8	10	8	0.476
5	1.0	10	10	0.591
6	1.2	10	12	0.689
7	1.4	10	14	0.781
8	1.6	10	16	0.891
9	1.8	10	18	0.991
10	2.0	10	20	1.099

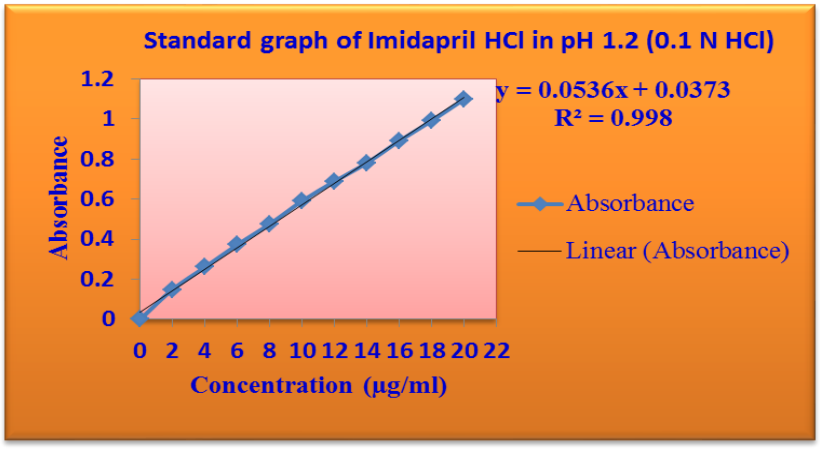

Fig.6: Standard calibration curve of Imidapril HCl in 0.1 N HCl.

Table.2: Data of Standard graph of Imidapril HCl in Distilled water at 319 nm.

Flask no	Volume of Stock-II (ml)	Volume made up to (ml)	Concentration (µg/ml)	Absorbance at 319 nm
1	0.2	10	2	0.036
2	0.4	10	4	0.109
3	0.6	10	6	0.175
4	0.8	10	8	0.252
5	1.0	10	10	0.324
6	1.2	10	12	0.398
7	1.4	10	14	0.463

8	1.6	10	16	0.523
9	1.8	10	18	0.599
10	2.0	10	20	0.678

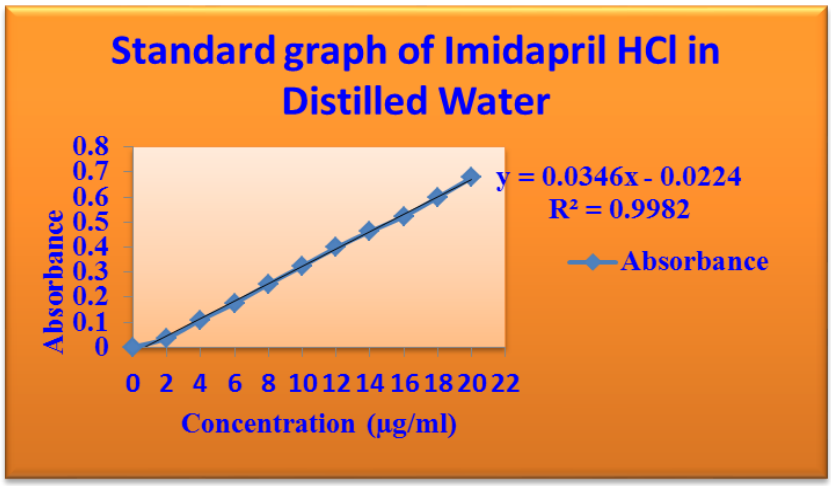

Fig.7: Standard graph of Imidapril HCl in distilled water at 319 nm.

Table.3: Data of Standard graph of Imidapril HCl in 0.1N NaOH at 236 nm.

Flask no	Volume of Stock-II (ml)	Volume made up to (ml)	Concentration (µg/ml)	Absorbance At 236 nm
1	0.2	10	2	0.04
2	0.4	10	4	0.091
3	0.6	10	6	0.161
4	0.8	10	8	0.215
5	1.0	10	10	0.282
6	1.2	10	12	0.351
7	1.4	10	14	0.397
8	1.6	10	16	0.453
9	1.8	10	18	0.525
10	2.0	10	20	0.604

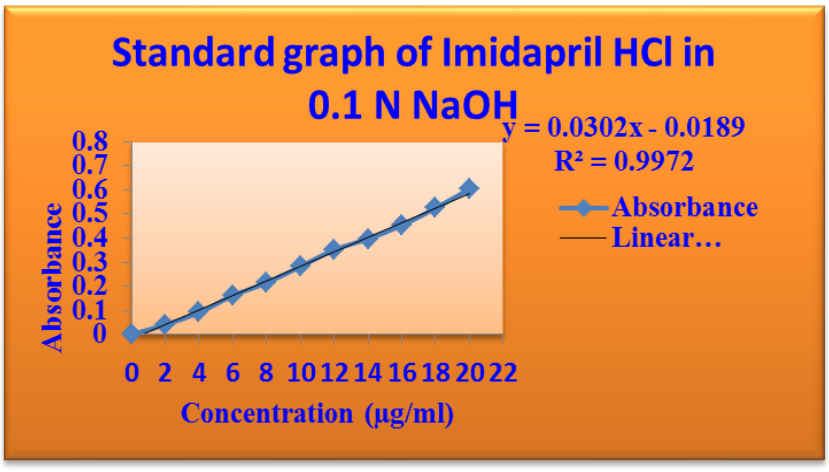

Fig.8: Standard graph of Imidapril HCl in 0.1N NaOH at 236 nm.

Method precision

The precision of proposed method was determined by Intra-day and Inter-day precision, and it was expressed in terms of percent relative standard deviation (% RSD). For Inter-day and Intra-day percentage RSD were found in the range of 0.048 at 4 µg/ml, 0.036 at 8 µg/ml and 0.070 at 4 µg/ml, 0.052 at 8 µg/ml respectively as shown in table 4.

Table.4: Determination of Precision.

Amount taken (µg/ml)	Intraday precision		Inter day precision	
	Amount found	% RSD*	Amount found	% RSD*
4	3.99	0.070	3.95	0.048
4	3.96	0.070	3.92	0.048
4	3.97	0.070	3.93	0.048
8	7.98	0.052	7.96	0.036
8	7.96	0.052	7.94	0.036
8	7.98	0.052	7.95	0.036

***RSD:** Relative standard deviation

Table.5: Summary of analytical parameters of Imidapril HCl in different solvents.

Parameter	0.1N HCl*	Distilled Water	0.1N NaOH*
Absorption maximum (λ_{max}) nm*	217	293	236
Beer's range (µg/ml)	2-20	2-20	2-20
Correlation co-efficient (R^2)	0.998	0.998	0.997
Regression	y = 0.053x + 0.037	y = 0.034x + 0.022	y = 0.030x + 0.018
Intercept	0.037	0.022	0.018
Slope (m)	0.053	0.034	0.030

*__HCl-__ Hydrochloric Acid, *__NaOH-__ Sodium Hydroxide, *__nm-__ Nano meter

CONCLUSION

The drug of Imidapril HCl exhibited different wavelength and absorbance in different solvents because of the change of chromophoric groups; it is called as the effect of solvent on absorption maximum of Imidapril HCl. Thus the conclusion was made that the proposed UV Spectrophotometric method were found to be simple, rapid, accurate, precise, linear and more economical method has been developed for the quantitative estimation of Imidapril HCl in bulk. The method is validated as per the ICH guidelines, and it is found that the developed method is robust and sensitive. Hence, this method can be successfully and suitably acquired for routine quality control analysis of Imidapril HCl in bulk.

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