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Development and Validation of UV Spectrophotometric Area Under Curve Method for Estimation of Eletriptan Hydrobromide

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ABSTRACT

A simple, accurate, precise, reproducible and economical AUC method has been developed for estimation of Eletriptan Hydrobromide from bulk and pharmaceutical formulation. The principle of area under curve method is "The area under two points on the mixture spectra is directly proportional to the concentration of the drug of interest. The λ max Eletriptan Hydrobromide in water was found to be 221nm. The proposed method was based on area under curve of UV spectrum between 216 nm to 226 nm and validated as per ICH guideline Q1 [R_1]. The drug follows linearity in the range of 5-25µg/ml with correlation coefficient value 0.999. And percent amount of drug estimated 98-102%. The accuracy method was checked by recovery experiment performed at three levels i.e. 80%, 100% and 120%. The recovery was found to be in the range of 98-102%.The low value of %RSD are indicated of the accuracy and reproducibility of the method. The precision of the method was studied as an intra and inter day variations and reproducibility. The ruggedness of the proposed method was studied with the help of two analysts; the above method was a rapid and cost effective quality control tool for routine analysis of Eletriptan Hydrobromide in bulk and pharmaceutical dosage form.

INTRODUCTION

Eletriptan is chemically a designated as (R) -3-[{1-Methyl-2-pyrrodinyl} methyl]-5-[2-phenyl sulfonyl ethyl]-H indol mono hydrobromide. Eletriptan Hydrobromide is a 5-Hydroxytryptamine 1B|1D receptor agonist. Eletriptan binds with high affinity to 5-HT1B, 5-H1D and 5-HT1F receptor, has modest affinity for 5-HT1A, 5-HT1E, 5-HT2B, and 5-HT7 receptors. Its pharmacological effects include the constriction of cerebral blood vessels and neuropeptides secretion blockade which eventually relives the pain. Eletriptan hydrobromide was rapidly absorbed and extensively cleared by metabolism.

Literature survey revealed that very few analytical methods has been reported for the determination of Eletriptan in pure drug, pharmaceutical dosage form and in biological sample using HPLC methods, but no AUC method was proposed by using the distilled water as solvent. The aim of the present work is to develop and validate a simple, fast, reliable and appropriate UV spectroscopic method confirmation of the applicability of the developed method was validated according to International Conference on Harmonization (ICH) guidelines for the determination of Eletriptan in bulk sample and in tablet dosage form.

MATERIALS:

Active pharmaceutical ingredient (API) of Eletriptan Hydrobromide was supplied as a gift sample from Enaltec lab. Ambernath (Mumbai, MS, India) commercially available tablet (Elipran) contains 20mg of Eletriptan Hydrobromide were obtained from local pharmacy.

INSTRUMENT:

Shimadzu UV 800 (Japan) with quart cells, connected to computer loaded with UV probe software, single pan electronic balance, sonication of the solution was carried out using an Ultrasonic cleaning bath.

PREPARATION OF STANDARD STOCK AND WORKING STANDARD SOLUTION:

The standard stock solution of Eletriptan Hydrobromide was prepared by dissolving accurately weighed 10mg of drug in water and diluted to 100ml with same solvent to obtain a final concentration of 100 µg/ml.

Selection of wavelength range:

The standard solution of 10µg/ml was scanned between 400nm-200nm in UV spectrophotometer against water as blank after baseline correction. Wavelength was selected around wavelength maxima (221nm). Different working standard were prepared between 5-25µg/ml. The various wavelengths were tried and final range between 216nm -226nm was selected on the basis of linear relationship between area and corresponding concentration.

Method: Area under curve

The AUC (Area under curve) method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between the two selected λ_1 and λ_2. Area calculation processing item calculate the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which area has calculated.

Validation of the Method:

The method was validated in terms of linearity, accuracy, precision, repeatability and ruggedness.

Linearity:

The linearity was determined by using working standard solutions between 5-25µg/ml. The spectrums of these solutions were recorded and area under curve was integrated in wavelength range 216nm - 226nm. Calibration curve of area under curve VS concentration was plotted was after suitable calculation and simple linear regression was performed (Figure 1). Regression equation and correlation coefficient were obtained. The range of equation has been decided according to statistical parameters of generated equations.

Accuracy:

The accuracy for the analytical procedure was determined at 80, 100, and 120 percent. Three determinations at each level were performed and % RSD was tabulated in Table 2.

Precision:

Precision of the method was studied as intra-day and inter-day variations. Intraday precision was determined by analyzing 5, 10, 15, 20 and 25µg/ml of Eletriptan Hydrobromide solutions for three times in the day. Intraday precision was determined analyzing the 5, 10, 15, 20 and 25µg/ml of Eletriptan Hydrobromide solutions daily for three days over the period of week.

LOD and LOQ: (Sensitivity)

The sensitivity of proposed method was estimated in terms of limit of detection (LOD) and limit of quantification (LOQ). The LOD and LOQ were calculated using equation LOD = 3.3 × S.D. / m. and LOQ = 10 × S.D. / m, Where "m" is the slope of corresponding calibration curve.

Repeatability:

Repeatability was determined by analyzing 15µg/ml concentration of Eletriptan Hydrobromide solutions for six times.

Ruggedness:

Ruggedness of proposed method is determined for 15µg/ml concentration of Eletriptan Hydrobromide by analyzing of dilution from homogeneous slot by two analyst using same operational and environmental conditions.

Determination of Eletriptan Hydrobromide:

Accurately weighed 10mg of drug was transferred to a 100ml volumetric flask and 50ml water was added. After shaking for 2min, the mixture was diluted up to mark with water from stock solution correct dilution was taken in such that the final concentration is 100µg/ml. The concentrations of the drug were calculated from linear regression equation. The resulting solution was scanned on UV range 400nm - 200nm, the spectrum was recorded at 221nm.

Application of Proposed Method For Pharmaceutical Formulation:

For analysis of commercial formulation twenty tablet of Eletriptan Hydrobromide (Elipran 20mg) was transferred to 100ml volumetric flask 50ml was added. After ultrasonic vibration for 20 min, the mixture was diluted up to mark with water. The whole solution filtered using

Whatman filter paper no. 42 from filtrate correct dilution was taken in such way that the final concentration is 100µg/ml. The concentrations of the drug were calculated from linear regression equation. The resulting solution was scanned on a spectrophotometer in the UV range 200nm -400nm. The spectrum was recorded at 221nm.

RESULTS AND DISCUSSION:

Method Validation:

The proposed method was validated as per ICH guidelines; the solutions of drugs were prepared as per the earlier adopted procedure gives in the experiment.

Linearity Studies:

The linear regression data for the calibration curve showed good linear relationship over the concentration range 5-25µg/ml for Eletriptan Hydrobromide (Figure 1). Linear regression equation was found to be $Y = 0.753x + 1.262$ ($r^2 = 0.999$) (Table 1).

Accuracy:

The solutions were reanalyzed by proposed method, result of recovery studies are reported in Table 2 which show that the percent amount found was between "98.00% – 102.00%" with % RSD less than 2.

Precision:

The precision of developed method was expressed in terms of % RSD. These result show reproducibility of the assay. The % RSD value found to be less than 2, so that indicate this method is precise for the determination of both drugs in formulation. (Table 3)

LOQ and LOD: (Sensitivity)

The LOD and LOQ for Eletriptan Hydrobromide found to be 5.77µg/ml and 1.90µg/ml. (Table 4)

Repeatability:

Repeatability was determine by analyzing 15µg/ml concentration of Eletriptan Hydrobromide solution for six times and the % amount found was between "98.00% – 102.00%" with % RSD less than 2.

Ruggedness:

The peak area measure for same concentration solution six times. The results are in the acceptable range for both drugs. The results are given in Table 4. The results showed that the % RSD less than 2. (Table 5)

Application of proposed method for pharmaceutical formulation:

The spectrum was recorded at 221nm. The concentrations of drug were calculated from linear regression equation the amount found was between 98.00% – 102.00% (Table 6).

CONCLUSION:

This UV spectrophotometric method is quite simple, accurate, precise, reproducible and sensitive. The UV method has been developed for quantification of Eletriptan Hydrobromide in tablet formulation. The validation procedure confirms that this appropriate technique for their quantification in formulation. It is also use in routine quality control of the formulations contains this entire compound.

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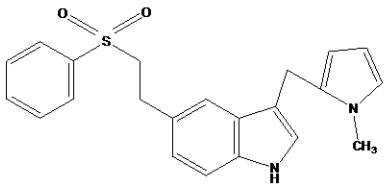

Figure 1: Structure of Eletriptan Hydro bromide

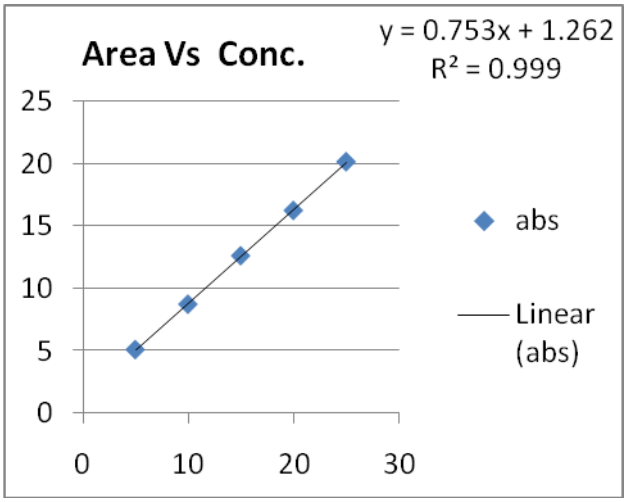

Figure 2: Calibration Curve of Eletriptan Hydro bromide (5-25 µg/ml)

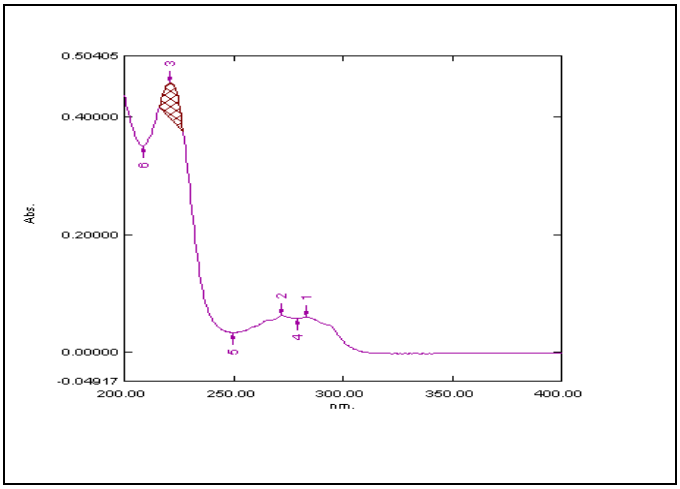

Figure 3: UV spectrum of Eletriptan Hydro bromide (10 µg/ml) in water.

Table 1: Linearity study of Eletriptan hydrobromide

Concentrations (µg/ml)	Absorbance Mean (n=3)	⁒ R.S.D
5	0.467	0.4393
10	0.832	0.4298
15	1.203	0.4358
20	1.548	0.4315
25	1.910	0.4353

Table 2: Recovery studies

Drug	Initial amount (µg/ml)	Amount added (µg/ml)	% Recovered	% R.S.D.
Eletriptan hydro bromide	10	8	98.01%	0.2387%
	10	10	100.05%	0.2437%
	10	12	99.72%	0.2429%

Table 3: Precision studies

Conc.(µg/ml)	Intra-day		Inter-day	
	Amt. Found	% R.S.D.	Amt. Found	% R.S.D.
5	100.06	0.2437%	101.4	0.2469%
10	98.97	0.2410%	99.06	0.2412%
15	99.50	0.2423%	100.17	0.2440%

Average of three estimations

Table 4: Sensitivity studies

LOD µg/ml	LOQ µg/ml
5.77	1.90

Table 5: Ruggedness studies

Component	Amount taken (µg/ml) (n=3)	Amount found (%)	
		Analyst-I ±SD	Analyst-II ±SD
Eletriptan hydro bromide	15	99.4210±0.2437	99.6802±0.2430

Table 6: Analysis of Eletriptan hydro bromide in Formulation

Conc. (µg/ml)	Amount found (%)	Mean Amount found (%)	(%) R.S.D.
10	99.5	99.4	0.2973(%)
	99.8		
	99.1		