

## METHOD DEVELOPMENT AND VALIDATION OF ELETRIPTAN HYDROBROMIDE TABLETS BY UV-VISIBLE SPECTROPHOTOMETRIC METHOD

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### ABSTRACT

Simple, accurate, precise, linear and reproducible method was developed for the estimation of Eletriptan hydrobromide pharmaceutical dosage forms by UV-Visible spectrophotometric method. The stock solutions were prepared by using combination of ethanol and distilled water. The absorbance of Eletriptan hydrobromide was found to be at 221nm. The calibration curve was plotted in the concentration range of 1-10 $\mu$ g/ml. In tablets Eletriptan hydrobromide percentage purity was estimated to be 99.65%. The results of analysis were validated according to ICH guidelines and were found to be satisfactory. Hence, present studies give excellent method for the determination of Eletriptan hydrobromide tablets.

**Keywords:** Eletriptan hydrobromide, Ethanol, Distilled water, spectrophotometer.

### INTRODUCTION

Eletriptan hydrobromide <sup>1</sup> is a 5-Hydroxytryptamine<sub>1B/1D</sub> receptor agonist. Eletriptan binds with high affinity to 5-HT<sub>1B</sub>, 5-HT<sub>1D</sub> and 5-HT<sub>1F</sub> receptors, has modest affinity for 5-HT<sub>1A</sub>, 5-HT<sub>1E</sub>, 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors. Eletriptan is chemically designated as (R)-3-[(1-Methyl-2-pyrrolidinyl)methyl]-5-[2-(phenylsulfonyl)ethyl]-1*H*-indolemonohydrobromide. Literature survey has revealed the availability of few spectrophotometric and HPLC methods but no spectrophotometric methods were proposed by using the combination of ethanol and distilled water as solvent. Hence the present work has been carried out.

### MATERIALS

Shimadzu 1800 UV-Visible spectrophotometer<sup>2</sup> was used for the

present study. Matched cells made of quartz of 1cm thickness were used. Pure form of the drug was obtained from shreeji Pharma International, Vadodara, Gujarat. Analytical grade ethanol and distilled water were used for the present study.

### METHOD<sup>3,4</sup>

An accurately weighed quantity of about 100mg of pure Eletriptan hydrobromide was dissolved in 50ml of Ethanol and 50ml of distilled water in a 100ml volumetric flask to get a concentration of 1000  $\mu$ g/ml as primary stock solution.

From primary stock solution 10ml was pipetted out into a 100ml volumetric flask and volume was made up to 100ml with 50ml Ethanol and 50ml distilled water to get a concentration of 100  $\mu$ g/ml.

The secondary stock solution was scanned over a wavelength range of 200-

400nm. The maximum absorption was found to be at 221nm. Results are given in Fig1.

### ESTIMATION OF ELETRIPTAN HYDROBROMIDE IN TABLET DOSAGE FORM

Tablets containing Eletriptan (40mg) were weighed and powdered. The powder equivalent to 50.2 mg of the drug was weighed and taken in 100ml volumetric flask and dissolved with a combination of 50ml Ethanol and 50ml distilled water and the volume was made up to the mark. From the resulting solution 1ml is pipetted out into a 100ml volumetric flask and the volume is made up to 100ml with 50ml ethanol and 50ml distilled water. The resulting solution is scanned over a wavelength region of 221nm. The concentration of the drug is calculated from the results. Results are given in Table 1.

### VALIDATION PARAMETERS

#### Accuracy<sup>5,6</sup>

Accuracy of the proposed method was ascertained by performing recovery studies by standard addition method. To the 2 µg/ml solution of the bulk drug solution predetermined concentration of the drug was added and the percentage recovery was calculated by measuring the absorbance at 221nm. Results are given in Table 2.

#### Precision

It is determined by repeatability, interday precision for the drug. 2µg/ml concentration was taken and its absorbance is measured at 221nm at different time intervals and its standard deviation and RSD is calculated. Results are given in Table 3.

### Linearity

Appropriate aliquots from the secondary stock solution was prepared to obtain concentrations of 1-10 µg/ml and their concentrations were determined. Calibration curve was plotted between absorbance and concentration. For the linearity study, aliquots of the drug solution were further diluted to get concentration range of 1-10 µg/ml. The calibration curve is obtained by plotting concentration versus absorbance. Coefficient correlation is calculated from it. Results are given in Table 4 and Fig 2.

### RESULTS AND DISCUSSION

There is no official method reported for the estimation of Eletriptan hydrobromide using ethanol and water as solvent. Hence the objective of the method was to develop simple, precise, accurate, sensitive, rapid and economical Uv-Visible spectrophotometric method for the estimation of Eletriptan hydrobromide tablet formulation. The method was based on the development of calibration curve equation in the quantization mode of the spectrophotometer.

The method for the estimation of Eletriptan hydro bromide in tablet form was found to be precise, accurate and reproducible. The linearity of the method is found in the Concentration range of 1-10µg/ ml .It indicated that the concentrations of Eletriptan had good linearity. The precision of the method is confirmed by repeatable analysis. . The % RSD was found to be 0.496 %.It indicated that the method has good precision. The low % RSD value indicated that there is no interference due to excipients used in formulation. Hence, the accuracy of the method was confirmed.

Table 1: Assay of Tablets

No. of tablets	Labeled amount	Amount found	%of label claim
20 Tablets	40mg	39.86mg	99.65

**Table 2: Accuracy and recovery studies**

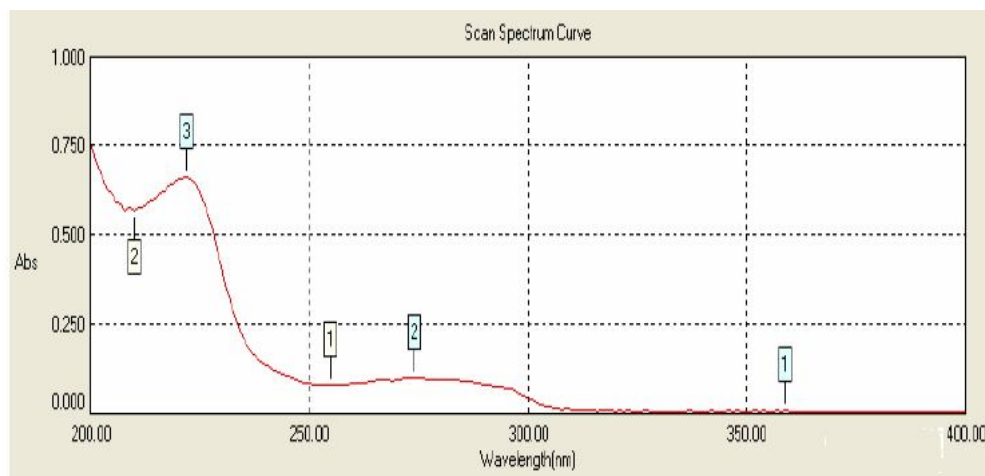
S. No.	Concentration	% of concentration added	Amount of concentration added	Amount recovered	Percentage of recovery	%RSD
1	2µg/ml	80%	1.6	2.9	80.55	0.709314
2		100%	2	1.89	94.5	0.501453
3		120%	2.4	2.7	61.36	0.353357

**Table 3: Precision studies**

S. No.	Concentration	Absorbance(nm)	Mean	SD	%RSD
1	2µg/ml	0.446	0.450333	0.00225	0.49963
2		0.45			
3		0.452			
4		0.451			
5		0.452			
6		0.451			

**Table 4: Linearity studies**

S. No.	Concentration(µg/ml)	Absorbance(nm)
1	1	0.101
2	2	0.233
3	3	0.342
4	4	0.427
5	5	0.571
6	6	0.661
7	7	0.772
8	8	0.895
9	9	0.932
10	10	1.05

**Fig. 1: Spectrum of Eletriptan hydrobromide**

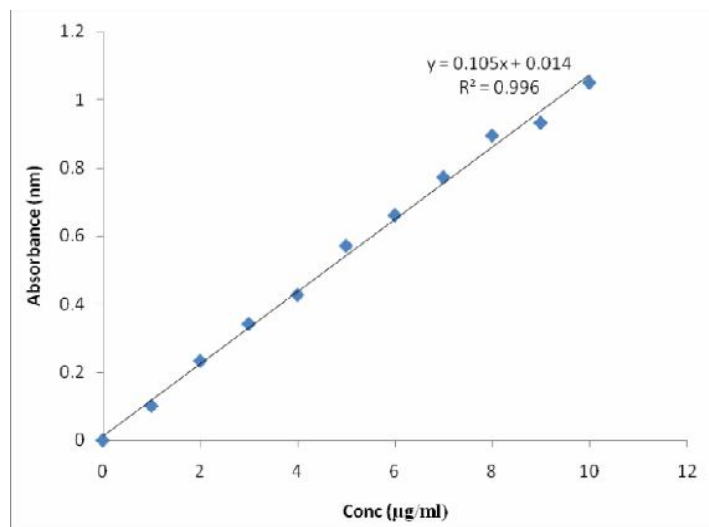


Fig. 2: Calibration curve

### CONCLUSION

The present method developed was simple, precise, accurate, sensitive, rapid and economical for the estimation of Eletriptan hydro bromide tablets by UV-Visible spectrophotometric method.

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