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Simple Spectrophotometric Method for Estimation of Frovatriptan Succinate in Bulk Drug and Pharmaceutical Formulation

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Subject: Quality Assurance

Abstract

UV Spectrophotometric method was developed for estimation of Frovatriptan Succinate in bulk drug and formulation. The method was validated as per ICH guidelines and found to be simple, rapid and reproducible. The method involved determination of wavelength maxima of drug in aqueous solvent and measurement of absorbance of various dilutions at corresponding wavelength. Beer's law was obeyed in concentration range of 2 to 7 µg/ml. The developed method was applied successfully to the determination of Frovatriptan Succinate in pharmaceutical formulation with good accuracy and precision.

Keyword: *Frovatriptan Succinate, first order derivative spectroscopy, method validation, UV spectrophotometer*

Introduction

Frovatriptan Succinate is a selective 5-hydroxy-tryptamine (5-$HT_{1B/1D}$) receptor Subtype agonist. Frovatriptan Succinate is chemically designated as R-(+) 3-methylamino-6-carboxamido-1, 2, 3, 4-tetrahydrocarbazole Succinate [1]. It is used in treatment of migraine headaches, in particular those associated with menstruation. Frovatriptan is 5-HT receptor agonist that binds with high affinity for 5-HT_{1B} and 5-HT_{1D} receptors. It has no significant effects on GABA mediated channel activity and has no significant effect on affinity for benzodiazepine binding sites. Frovatriptan acts on extra cerebral, intracranial arteries and inhibits excessive dilation of these vessels in migraine [1, 2]. Frovatriptan Succinate has been estimated by various techniques. However, there are a limited number of published papers related to UV Spectrophotometric technique of evaluation of the drug. Derivative Spectrophotometric method is a useful technique for qualitative and quantitative analysis and helps in reducing the effects of spectral background interferences [3, 4]. Derivative spectroscopy is very useful in qualitative analysis, either for characterizing materials or for identification [5]. In the present study first order derivative method for a direct determination of Frovatriptan Succinate in bulk drug and pharmaceutical formulation namely suppository has been developed [3-6].

Materials and Methods

Instrumentation:

All Spectrophotometric measurements were performed on LABINDIA UV 3000^+ spectrophotometer with 1.0 cm quartz cuvettes. Instrumental conditions were: wavelength range 200-400 nm. Scan rate 1000 nm/min; slit 1.0 nm. Weighing was done on single pan balance (Shimadzu AUY 220).

Reagents and Chemicals:

Frovatriptan Succinate was procured as gift sample from Indeus Life Sciences Pvt Ltd (Mumbai). All other reagents are of Analytical Grade. Distilled water was used throughout the experiment. Suppository formulation containing Frovatriptan Succinate was developed inhouse. Each suppository contains 6 mg of Frovatriptan Succinate.

Standard solution:

Accurately weighed 100 mg of Frovatriptan Succinate was transferred into 100 ml volumetric flask and diluted up to the mark with 0.1 N HCl to get stock (1) solution containing 1000 µg/ml of Frovatriptan Succinate.

One ml from stock (1) was pipetted out and diluted to 100 ml with 0.1 N HCl up to mark to get 10 µg/ml drug stock (2). Aliquots of 2, 3, 4, 5, 6 and 7 ml of these solutions were transferred into 10-ml volumetric flasks and diluted with 0.1 N HCl up to 10 ml. The spectra were recorded using 0.1 N HCl as a blank.

Analysis of Frovatriptan Succinate suppository:

Suppository containing 6 mg of Frovatriptan Succinate was transferred into a 100 ml of volumetric flask. The solid suppository was melted on water bath at temperature 90^0C to 100^0C and homogenized after addition of 0.1 N HCl. The sample was cooled to room temperature and the volume adjusted to 100 ml with 0.1 N HCl (60 µg/ml). The solution was filtered through Whatmann filter paper. One ml of solution was pipette out from stock and diluted to 10 ml with 0.1 N HCL. A concentration of 6µg/ml was achieved. The sample solution was scanned in the wavelength range of 200–400 nm using 0.1 N HCl as a blank [6, 7].

Result

Absorption maxima of Frovatriptan Succinate in 0.1 N HCl was seen at 245 nm (Figure 2).

Method validation

The method was validated as per ICH guidelines for linearity, precision, accuracy, LOD and LOQ [7-12].

Linearity:

Linearity was evaluated by analyzing different concentration of standard solution of Frovatriptan Succinate (10 µg/ml). Beer Lambert's law was obeyed in the concentration range of 2 to 7 µg/ml. The results obtained were tabulated and calibration curve of absorbance versus concentration was plotted. The slope of the calibration curve and coefficient of regression were determined (Table 1).

Precision:

The intraday precision study of Frovatriptan Succinate was carried out by estimating different concentrations of Frovatriptan Succinate (2 to 7µg/ml), three times on the same day and the results are reported in terms of % RSD. The results are given in Table 2.

Accuracy:

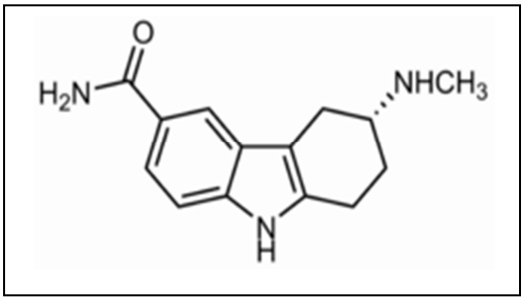
Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts of the drugs to the formulation. Recovery was checked at three levels, 80%, 100%, and 120%. The results are shown in Table 3.

Limit of Detection and Limit of Quantitation:

LOD and LOQ were calculated from the data obtained in linearity studies. The slope of linearity plot was determined. For each of the six replicate determinations, y intercept was calculated and standard deviation of the y intercept was computed. From these values, the parameters Limit of Detection (LOD) and Limit of Quantitation (LOQ) were determined on the basis of response and slope of the regression equation. The result is given in Table 1.

Discussion:

The method developed for estimation of Frovatriptan Succinate in pharmaceutical dosage form was found to be accurate, simple, rapid and reproducible. Hence it can be used for routine analysis of this drug in pharmaceutical dosage forms. No interference due to suppository excipients was observed. The values of % RSD and correlation of coefficient were found to be 0.5650 and 0.9976 respectively for Frovatriptan Succinate. The result of accuracy studies for drug was found to be 99.63%. Both methods are accurate, simple, rapid, precise, reliable, sensitive, reproducible and economic and are validated as per ICH guidelines.



(+)-(*R*)-3-methylamino-6-carboxamido-1, 2, 3, 4-tetrahydrocarbazole succinate

Fig.1 Structure of Frovatriptan Succinate

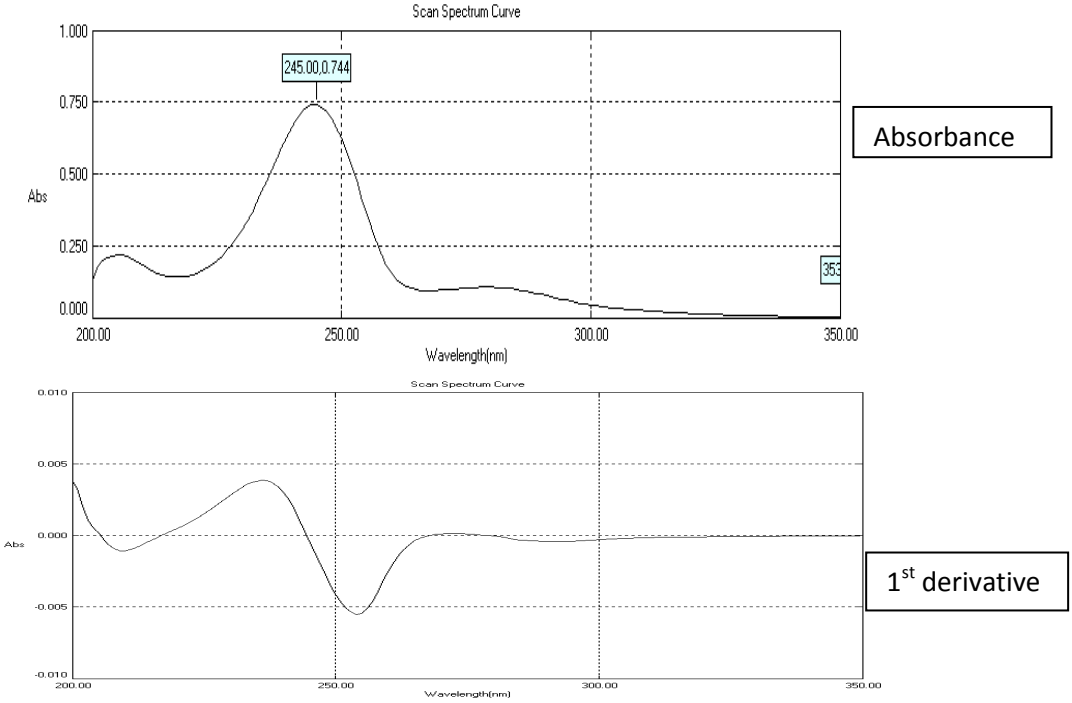


Fig. 2 Difference absorbance and 1st order Derivative spectra of Gaussian band

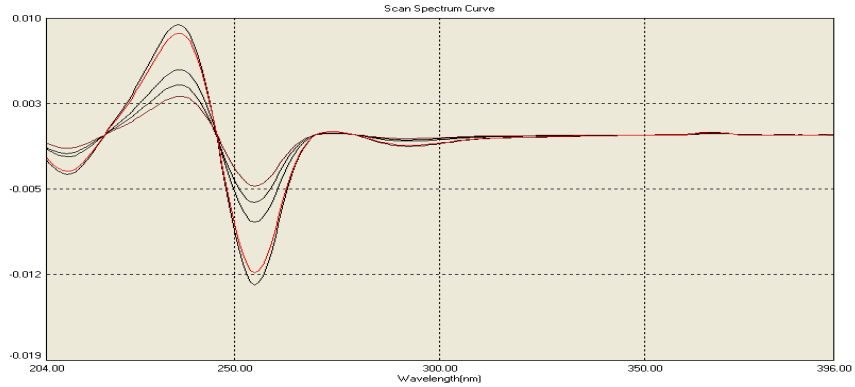


Fig. 3 First-order derivative spectrum of Frovatriptan Succinate

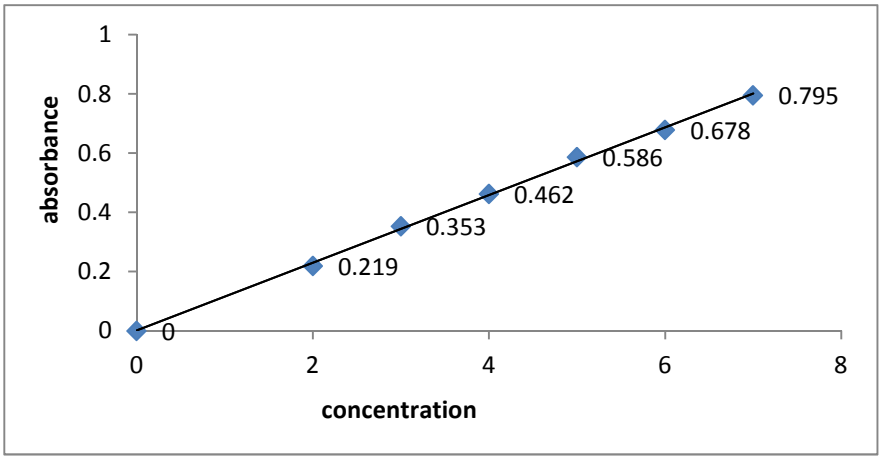


Fig. 4 Calibration curve for Frovatriptan Succinate

Table 1: Optical Characteristics of Frovatriptan Succinate

Parameters	1st Order Derivative Method
ʎ max (nm)	245
Equation	y = 0.1141x + 0.0017
r^2 value	0.9976
Slope	0.1141
Intercept	0.0017
Linearity	2-7 µg/ml
LOD (µg/ml)	0.0587
LOQ (µg/ml)	0.178

Table 2: Intraday data of precision

Sr. no	Concentration (µg/ml)	% Recovery
1	2	98.32%
2	3	98.54%
3	4	97.45%
4	5	98.69%
5	6	99.11%
6	7	98.33%

Table 3: Accuracy

Level of % Recovery	Concentration taken (µg/ml)	Concentration estimated (µg/ml)	%Analytical recovery	Average% recovery
80	5	4.9924	99.85%	99.63%
100	6	6.0512	100.85%	
120	7	6.8747	98.21%	

Conclusion

Our study indicates that the proposed UV spectroscopic method is simple, rapid, precise and accurate. The developed UV spectroscopic methods were found suitable for determination of Frovatriptan Succinate in bulk drug and in formulation without any interference from excipients. Statistical analysis proves that, these methods are repeatable and selective for the analysis of Frovatriptan Succinate. Therefore we can conclude that these methods can be used for routine evaluation of samples containing Frovatriptan Succinate.

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