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RESEARCH ARTICLE

VALIDATED SPECTROSCOPIC METHOD FOR ESTIMATION OF FROVATRIPTAN SUCCINATE IN BULK DRUG AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A simple efficient, precise and accurate spectroscopic method has been developed and validated for quantitative estimation of frovatriptan succinatein bulk drug and pharmaceutical dosage form. Frovatriptan succinate is dissolved in distilled water and the resulting solution was then scanned in the UV range (200-400nm) in a 10 mm quartz cell in a double beam UV spectrophotometer. The λmax of Frova was found to be 244nm.The method obeys Beers law in the concentration range from 2-10µg/ml. The correlation coefficient was found to be 0.9999 (r^2= 0.9999). The LOD and LOQ were found to be 0.4362 and 1.3265µg/ ml respectively. The result of estimation of marketed tablet formulation (FROVA) was found to be 99.47% with their % RSD 0.4362.The accuracy of the method was determined by recovery studies. The percentage recovery was found to be 99.83%. The method was validated statistically as per ICH guidelines. The method showed good reproducibility and recovery with % RSD less than 2. So, the proposed method was found to be simple, specific, precise, accuracy, linear, and rugged. Hence it can be applied for routine analysis of Frovatriptan in bulk drug and the Pharmaceutical formulations.

Keywords: frovatriptan; spectroscopic method; Tablet dosage forms

INTRODUCTION

FROVA (frovatriptan succinate) tablets contain frova (frova (frovatriptan succinate) triptan succinate) triptan succinate, a selective 5-hydroxy-tryptamine$_1$ (5-HT$_{1B/1D}$) receptor subtype agonist, as the active ingredient. Frova (frova (frovatriptan succinate) triptan succinate) triptan succinate is chemically designated as R-(+) 3-methylamino-6-carboxamido-1, 2, 3, 4-tetrahydrocarbazole monosuccinate monohydrate[1-4] fig-01. The review of literature revealed that UV methods [5-6] were reported for the estimation of frovatriptan succinatein bulk and tablet formulations.

OBJECTIVE : To develop a simple, precise and accurate spectroscopic method for the estimation of Frova in Pharmaceutical formulation. The method was validated according to ICH guidelines[7-8]. Thus the objective of present study was developed and applicable for the routine analysis of Frova in tablet formulations.

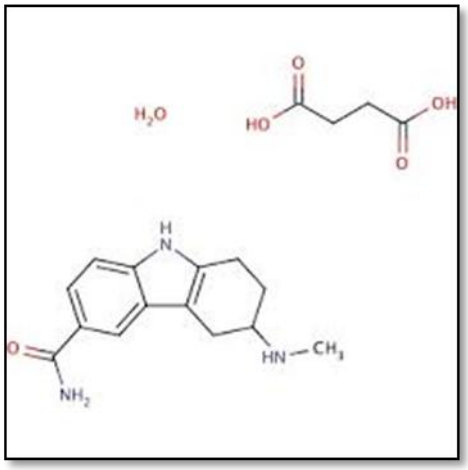

Fig.1.Chemical structure of frovatriptan succinate

EXPERIMENTAL METHODS

Instrumentation and analytical conditions: The validated method utilized a Shimadzu UV-1800 UV/VIS spectrophotometer with 1cm matched quartz cells was used for spectral and absorbance measurements at ambient temperature. The absorbance was measured at 244 nm shown in fig-02.

Stock and working standard solutions: Weigh accurately 15mg of Frovatriptan raw material and transferred into the 100 ml volumetric flask dissolved and made up to 100 ml with distilled water. The solution was observed to contain 150 µg/ ml.

The above stock solution (0.5–3.0ml of 150µg/ ml) was transferred into six 100 ml volumetric flasks and made up to mark with distilled water. The absorbance of resulting solutions was measured at 244nm using distilled water as blank. Calibration curve was plotted by using concentration Vs absorbance. The curve was linear with the concentration range of 2-10 µg/ ml.

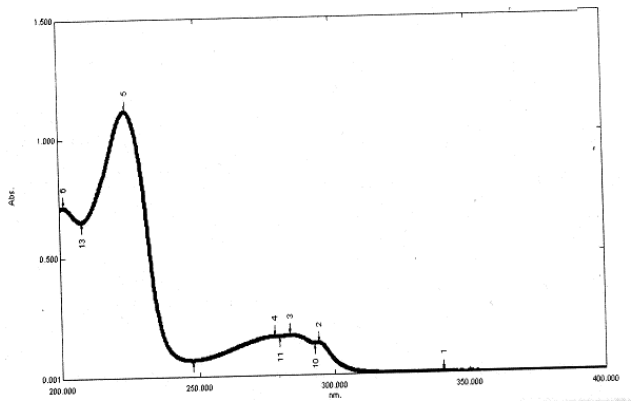

Fig.2.UVAbsorbance Spectrum for frovatriptan succinate

Assay of sample preparation: Twenty commercial tablets (labeled concentration 2.5 mg of Frova) were weighed and their mean mass was determined. Triturate the tablets into a fine powder in a glass mortar. 15 mg of equivalent Frova formulation was taken into a series of three 100 ml standard flasks**.** To that 2.5 mg, 5 mg and 7.5 mg of raw material were added in to series of standard flasks 1, 2 and 3, respectively. Dissolved with distilled water and made up to volume with distilled water The solutions were sonicated for 10 minutes. After sonication, the solution was centrifuged at 100 rpm for 15min. The solutions were filtered through Whatmann filter paper No. 41.From each standard flask, 2 ml of the clear filtrate was transferred into a series of six 25 ml standard flasks and made up to volume with distilled water. The amount of drug recovered was calculated. Each concentration was repeated for three times. Finally the method was validated as per ICH guide lines for precision, accuracy, specificity, linearity, reproducibility, LOD and LOQ.

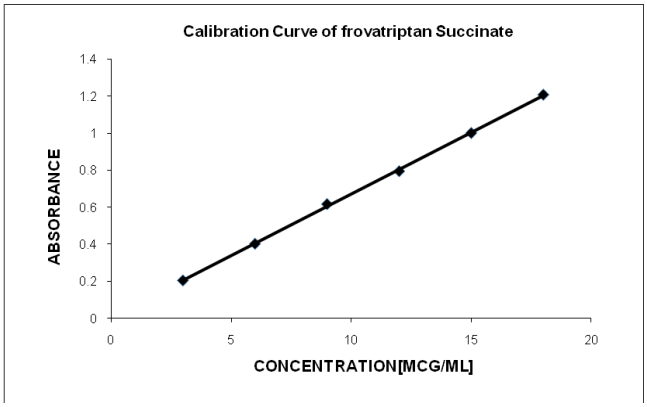

Fig 3.Calibration curve of frovatriptan succinate

Table: 01 Recovery studies of frovatriptan succinate.

Amount Present (µg/ml)	Amount added* (µg/ml)	Amount found* (µg/ml)	% recovery *	Average ± S.D	% RSD
12.03	2	14.01	99.05	99.83 ± 0.4362	0.4396
12.03	4	16.06	101.50		
12.03	6	17.93	98.96		

RESULTS AND DISCUSSION

A simple, selective, accurate, precise spectroscopic method for the estimation of Frova in bulk and tablet dosage form has been developed and validated. The linearity range in the concentration range of 2-10 µg/ ml (correlation coefficient= 0.9997).It indicated that the concentrations of Frova had good linearity. The LOD and LOQ were found to be 0.4362 and 1.3265µg/ ml respectively. The amount of Frova was calculated as 99.47%. Further the precision of the method was confirmed by the repeatable analysis of formulation. The percentage recovery was found to be in the range of 98.96- 101.50%.The procedure was repeated for 3 times for each concentration. The % RSD was found to be 0.4362%.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.

CONCLUSION

The proposed method is simple, accurate, precise and selective for the estimation of Frova in bulk and in tablet

dosage forms. The method is economical, rapid and do not require any sophisticated instruments contrast to chromatographic method. Hence it can be effectively applied for the routine analysis of Frova in bulk and in tablet dosage forms.

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