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Research Article

QUANTITATIVE UV SPECTROPHOTOMETRIC ESTIMATION OF SILDENAFIL CITRATE BY HYDROTROPIC TECHNIQUE

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ABSTRACT

A simple, sensitive, accurate, precise and eco-friendly UV spectrosphotometric method for sildenafil citrate was developed. In the present investigation, a 2.0 M sodium benzoate solution was employed as hydrotropic solubilizing agent to solubilize poorly water-soluble drug sildenafil citrate for its spectrophotometric analysis. Sildenafil citrate showed λ-max at 306 nm and beer's law was obeyed in the concentration range of 10 – 50 µg/ml. The results of analysis have been validated statistically and by recovery studies.

Keywords: Spectrophotometry, Sildenafil citrate, 2.0 M sodium benzoate solution, Hydrotrophy.

INTRODUCTION

Various techniques are employed to enhance the aqueous solubility of poorly water-soluble drugs[1]. Hydrotropic solubilization is one of them. Sildenafil citrate is designated chemically as 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazole [4,3-d] pyromidine-5-yl)-4-ethoxyphenyl] sulfonyl]-4- methylpiperazine citrate. Literature survey reveals that the drug can be estimated by spectrophotometric methods[2-6], extractive spectrophotometric methods[7,8] HPLC[9-12] and LC/MS/MS[13] methods. In the present investigation, hydrotropic solubilizing agent, 2.0 M sodium benzoate was employed to solubilize sildenafil citrate from the fine powder of its tablets to carryout spectrophotometric analysis.

MATERIALS AND METHODS

Instrumentation

The spectrophotometric measurements were carried out using an Elico UV/Visible double beam spectrophotometer SL-210 with 1 cm matched quartz cells. Digital Balance: BL-220H, Shimadzu was used.

Chemicals and sample

Sildenafil citrate pure drug sample was obtained as gift sample from aurobindo pharma, Hyderabad. Commercial tablets of sildenafil citrate were purchased from the local market. 144.11 g of sodium benzoate was dissolved in 500mL of distilled water to get 2.0 M sodium benzoate solution. The chemicals and solvents used were of analytical grade.

Procedure

50 mg of sildinafil citrate was weighed accurately and transferred into a 100 ml volumetric flask and solubilized by 50 ml of 2.0M sodium benzoate solutions and final volume was adjusted with distilled water to 100 ml (500 µg/ml). From the above solution 10 ml of solution was taken and diluted to 50 ml with distilled water to get a solution containing 100 µg/ml of sildenafil citrate. The stock solution was further diluted with distilled water to obtain various dilutions. Absorbance maximum of drug solution was found to be 306 nm (fig. 1).

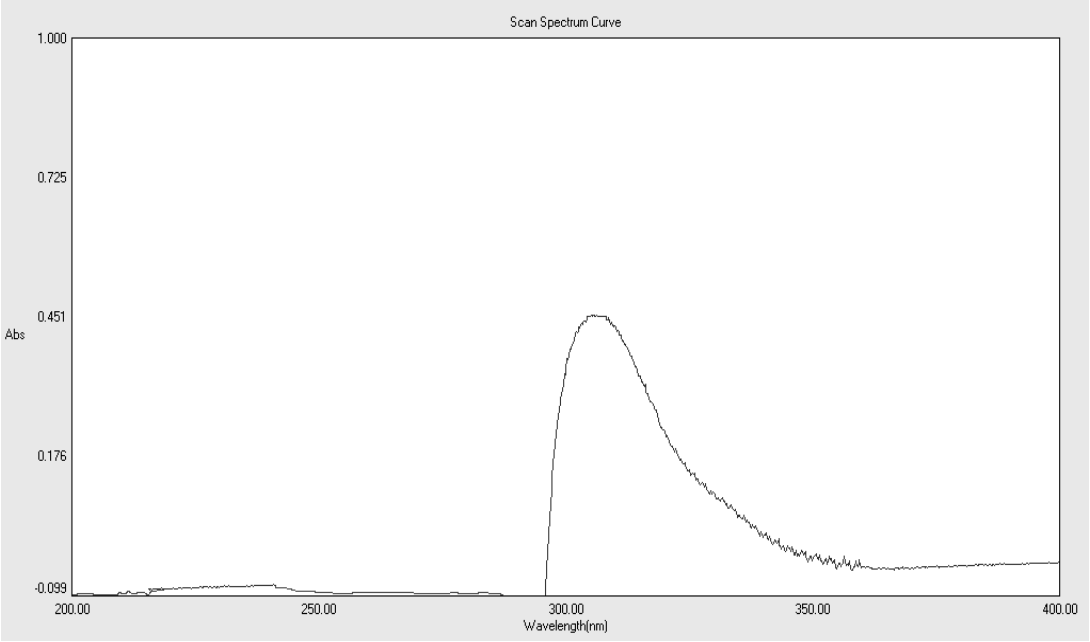

Fig. 1: UV spectrum of Sildinafil citrate in 2.0 M sodium benzoate solution.

Standard solutions of 10, 20, 30, 40 and 50 µg/ml of drug were used to plot the calibration curve by taking the absorbance at 306 nm against corresponding reagent blanks.

Analysis of the tablet formulations of the drug by proposed method

Twenty tablets were weighed and powdered. An amount of powder equivalent to 10 mg sildenafil citrate was accurately weighed and transferred to a 100 ml volumetric flask, to that 50 ml of 2.0 M sodium benzoate solution was added and the flask was shaken for about 25 min to dissolve the drug, and then filtered through Whatman No. 41 filter paper. Now the volume was made up to the mark with distilled water and suitable aliquots were analyzed using the method given above.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1.

Table 1: Optical characteristics of proposed method

Parameters	Values
λ_{max} (nm)	306
Beer's law limit (µg/ml)	10-50
Sandell's sensitivity (µg/cm^2/0.001 absorbance unit)	7.0177×10^{-2}
Molar absorptivity (l/mol/cm)	9.5310×10^3
LOD (µg/ml)	0.4482
LOQ (µg/ml)	1.3448
Regression equation (Y = mc + b)	
Slope (m)	0.015
Intercept(b)	-0.0098
Correlation coefficient (r^2)	0.999

The regression analysis was made; slope (m), intercept (b) and correlation coefficient obtained from different concentrations and the results are summarized in Table 1. Tablets containing sildenafil citrate were successfully analyzed by the proposed method. The results are represented in Table 2.

Table 2: Assay results, recovery and precision studies

Sample	Labeled amount (mg/ tablet)	(%) label claim* ± S.D	%Recovery	Precision S.D Inter-day (n=18)	Intra-day (n=6)
Sildinafil citrate Tablets	100	99.75 ± 0.090	99.92 - 100.12 %	0.2117	0.090

* Average of six determinations.

The method was validated for linearity, limit of detection (LOD), limit of quantification (LOQ), accuracy and precision. To ensure the accuracy of the results obtained, recovery experiments were performed by adding known amounts of pure drug to the previously analysed tablets and these samples were reanalysed by the proposed method. The percentage recoveries thus obtained were given in Table 2. None of the excipients usually employed in the formulation of tablets interfered in the analysis of sildenafil citrate, by the proposed method.

CONCLUSION

The proposed method of analysis is novel, simple, cost-effective, environment friendly, safe, accurate and reproducible. This method can be routinely employed in the analysis of sildinafil citrate in tablet formulations precluding the use of organic solvent.

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