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Quantitative spectrophotometric determination of sildenafil citrate in tablet formulation using urea as hydrotropic solubilizing agent

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ABSTRACT

A simple, safe and sensitive method of spectroscopic determination of sildenafil citrate in UV region was developed using 8 M urea solution as hydrotropic solubilizing agent. Sildenafil citrate showed λ-max at 293 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: Sildenafil citrate, hydrotropic solubilization, UV estimation.

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INTRODUCTION

The primary objective of the present investigation was to employ a hydrotropic solution to extract the drug from the fine powder of sildenafil citrate tablets, precluding the use of costlier organic solvents for spectrophotometric analysis. Costlier organic solvents are more often employed to solubilize the poorly water-soluble drugs for spectrophotometric analysis. Volatility and pollution are drawbacks of such solvents. Various techniques are employed to enhance the aqueous solubility of poorly water-soluble drugs[1]. Hydrotropic solubilization is one of them. Sildenafil citrate (SC) 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, 8 M urea was employed to solubilize SC from the fine powder of its tablets to carryout spectrophotometric analysis.

MATERIALS AND METHODS

T60 UV/Visible spectrophotometer with 1 cm matched quartz cells was used for spectrophotometric analysis. SC bulk drug sample was obtained as gift sample from Arabindo pharmaceuticals, Hyderabad. Commercial tablets of SC were purchased from the local market. All other chemicals and solvents used were of analytical grade.

Method of preparation of 8 M urea solution

Urea (120.12 g) was dissolved in 150 ml distilled water in a 500 ml beaker and volume was made up to 250 ml with distilled water.

Calibration curve

SC (50 mg) was accurately weighed and transferred in a 100 ml volumetric flask and 50 ml of 8 M urea was added and the drug was solubilized by shaking the flask. The volume was made up to the mark with distilled water. The stock solution was further diluted with distilled water to obtain various dilutions. 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 293 nm against corresponding reagent blanks.

Preliminary solubility studies

More than 20 fold enhancement in aqueous solubility of SC was found in 8 M urea solution (as compared to water solubility).

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Analysis of SC tablets

Twenty tablets of SC were weighed and finely powdered. Powder equivalent of 50 mg SC was accurately weighed and transferred to a 100 ml volumetric flask. To it, 50 ml of. 8 M urea solution was added. The flask was shaken briskly for 20 minutes and then volume was made up to the mark with distilled water. After filtration through Whatmann filter paper, the filtrate was appropriately diluted with distilled water and absorbance was noted at 293 nm against reagent blank. The drug content was determined using the calibration curve.

RESULTS AND DISCUSSION

Table-1. Optical characteristics of proposed method

Parameters	values
λ_{max} (nm)	293
Beer's law limit (µg ml^{-1})	10 - 50
Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit)	1.713×10^{-5}
LOD (µg/ml)	3.15
LOQ (µg/ml)	9.55
Molar absorptivity (L mol^{-1} cm^{-1})	1.16×10^{4}
Regression equation (Y = mx + b) Slope (m) Intercept (b)	 0.0184 -0.0187
Correlation coefficient (r^2)	0.998

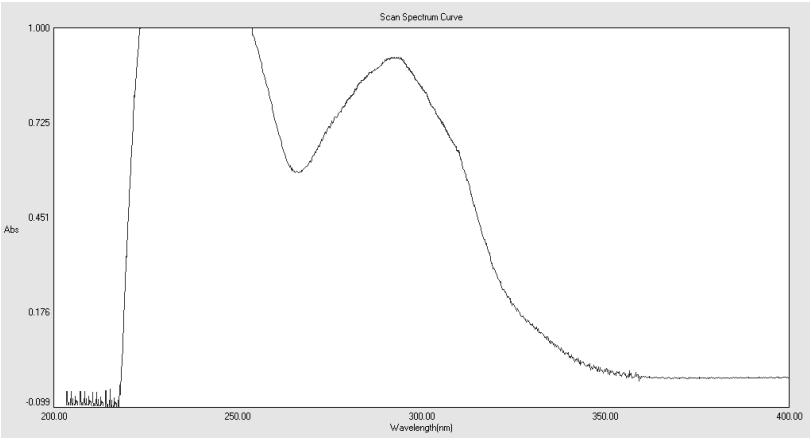

Figure 1. UV spectrum of sildenafil citrate in 8 M Urea.

The UV spectrum of SC in 8 M Urea has showed in figure1. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1.

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Table 2. Assay results, recovery and precision studies

Sample	Labeled amount (mg/ tablet)	(%) label claim* ± S.D	%Recovery (n=18)	Precision**		
				Repeatability	Inter-day	Intra-day
Sildinafil citrate tablets	100	99.97± 0.595	100.265	0.0087	0.0059	0.0021

*** Average of six determinations. **SD of five determinations.**

The regression analysis was made; slope (m), intercept (b) and correlation obtained from different concentrations and the results are summarized in Table 1. Tablets containing SC were successfully analyzed by the proposed method. The results are represented in Table 2. The method was validated for linearity, accuracy and precision. To ensure the accuracy and reproducibility of the results obtained, recovery experiments were performed by adding known amounts of pure drug to the previously analysed formulated samples and these samples were reanalyzed 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 SC, by the proposed method. The precision of the method was studied as intra-day, inter-day and repeatability. The % RSD values less than 2 indicate the method are accurate and precise.

CONCLUSIONS

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 SC in tablet formulations precluding the use of organic solvent.

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