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## Development of new and rapid method for UV spectrophotometric determination of sildenafil in marketed formulations

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### ABSTRACT

A simple, rapid, and sensitive UV spectrophotometric method has been developed and validated for the determination of sildenafil citrate in pharmaceutical preparations. The method was developed utilizing 1N Hydrochloric acid. The standard and sample was scanned and the absorbance is scanned at 233.6. Linearity was observed in the concentration range from 4-10 µg/ml with a correlation coefficient ( $R^2$ ) greater than 0.997. The method was validated by following the analytical performance parameters suggested by the International Conference on Harmonization (ICH). All validation parameters were within the acceptable range. Under experimental conditions described, calibration curve, assay of tablets and recovery studies were performed. Parameters of validation prove the precision of the method and its applicability for the determination of sildenafil citrate in pharmaceutical tablet formulations. The method is fast and is suitable for high throughput analysis of the drug.

**Key words:** Sildenafil citrate, Spectrophotometry, Validation, Correlation coefficient

### INTRODUCTION

Sildenafil citrate is designated chemically as 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazole[4,3-d]pyrimidine-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazinecitrate. Literature survey reveals that the drug can be estimated by spectrophotometric methods<sup>1-5</sup>, extractive spectrophotometric methods<sup>6,7</sup>, HPLC<sup>8-11</sup> and LC/MS/MS<sup>12</sup> methods. In the present investigation, INHCl is used in spectrophotometric estimation of drug which is safe and inexpensive when compared with existing method with methanol. It inhibits the enzyme PDE5 by occupying its active site. Sildenafil protects cyclic guanosine monophosphate (cGMP) from degradation. It is used topically for the treatment of ejaculatory dysfunction<sup>13</sup>. Male erectile dysfunction has been defined as the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance in affected patients<sup>14</sup>. Although male erectile dysfunction represents a major clinical problem, medical therapy for this condition remains unsatisfactory because it was invasive or ineffective before the introduction of sildenafil<sup>15</sup>.

## MATERIALS AND METHODS

### Materials and methods

#### Instruments used

1. Balance
2. Single pan electronic balance- sartorius GE412
3. UV visible spectrophotometer
4. UV visible double beam spectrophotometer
5. Systronics 2203(smart)
6. Matched quartz cells corresponding to 1 cm path length

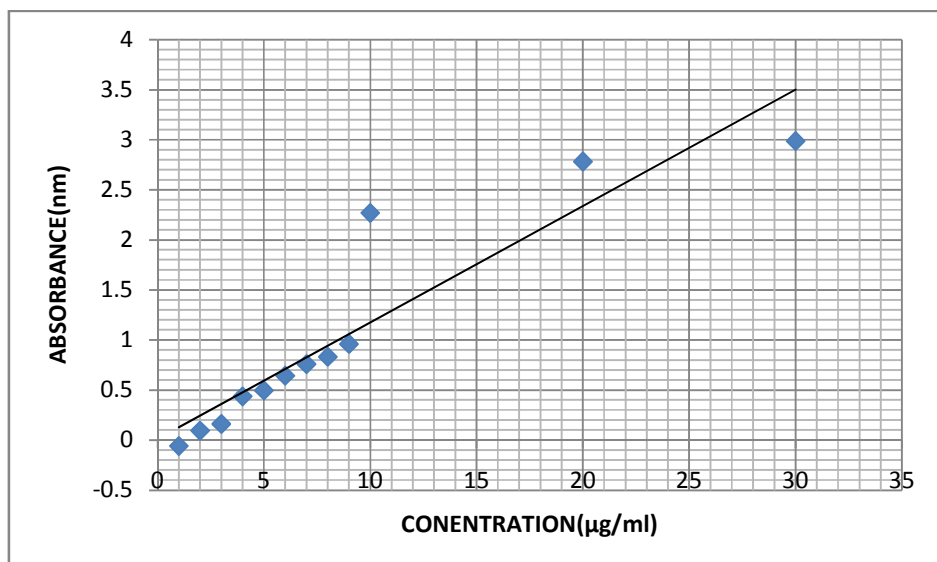
#### Reagents

1. 1N Hydrochloric acid
2. Reference standard Sildenafil

#### Tablets brands used

- Suhagra-100mg  
Vigora-100mg

TRADE NAME	COMPANY NAME	DOSE	BATCH NUMBER	MANUFACTURED DATE	EXPIRY DATE
SUHAGAR	CIPLA	100	AA0018	JAN10	DEC13
VIGORA	MANKIND	100	GR1015	JAN2011	DEC2012



Analysis of formulation

### Procedure:

#### Preparation of standard stock solutions:

The standard stock solution of drug was prepared by dissolving 50mg of the drug in 50 ml standard flask using water as a solvent to give a concentration of 1000 µg/ml. This stock solution on further dilutions are used for establishing following parameters.

#### Concentration of solvent and Wavelength selection:

Solutions of concentration of 9 µg/ml, 10 µg/ml, 20 µg/ml was prepared.

They were subjected to scanning from 200-400nm.

The dilutions were made using different normalities of hydrochloric acid namely 0.1N, 0.5N, 1N.

From the different absorbance values obtained 1NHCl and 233.6nm was selected for the present work.

*Beer's law range:*

The stock solution were suitably diluted with water to get concentration range from 1 to 1000 µg/ml. The solutions are scanned in UV regions between 200 to 300nm the absorption were measured at  $\lambda_{\text{max}}$  found. Using absorbance values against concentrations plotted the calibration curve and the linearity range can be found.

The proposed method is applied to the analysis of various marketed formulations

**RESULTS AND DISCUSSION**

1. The UV spectra of sildenafil were presented . the absorption maxima was observed at 236.6nm. Obeysance to beers law was confirmed by the linearity of the calibration curve of sildenafil. Sildenafil showed linearity in the concentration range of 4-10µg/ml.

2. The quantitative estimation was carried out in tablet formulations by taking concentrations of 4.0-9.0 µg/ml. The brands of formulations shows the percentage purity values range from 100 to 102 the percentage deviation values were found to be between 0.09 to 0.1.

3. The quantitative results obtained were subjected to statistical analysis to find out standard deviation and standard error values. The relative standard deviation values are below, indicating the precision of the methodology and low standard error values show the accuracy of the method.

4. The repeatability of the method was confirmed by the assay procedures with 3 different concentrations of 3 replicates each. The results obtained in repeatability test expresses the precision of the given method.

5. The validation of the proposed method was further confirmed by recovery studies. The recovery values vary from 99.54 to 101.27% w/w. This serves as a good index of accuracy and reproducibility of the study.

**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 sildenafil citrate in tablet formulations precluding using 1NHCl as a solvent.

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