Surfactant-based potentiometric method for quantification of sildenafil citrate

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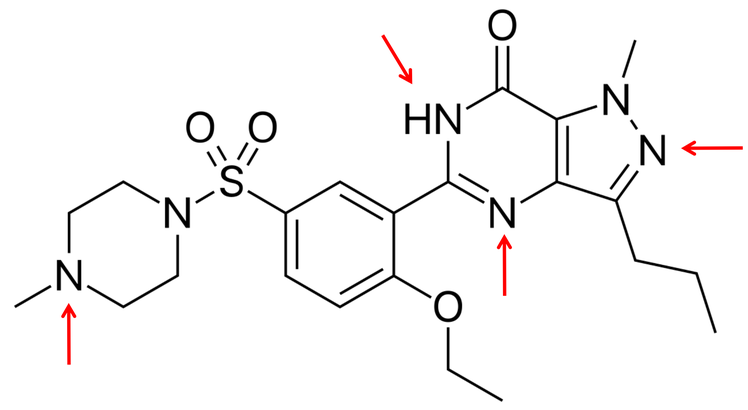
INTRODUCTION

Most of the proposed potentiometric methods for quantification of sildenafil citrate (SLC) employ a non-aqueous environment. The non-aqueous titrations have several drawbacks including the use of expensive organic solvents that are volatile and harmful for both the analyst and the environment, as well as the need to control the moisture, temperature and carbon dioxide levels. On the other hand, the method for determination of SLC described in the Ph. Eur. monograph 07/2017:2270 for Sildenafil citrate is high performance liquid chromatography (HPLC).

In order to overcome some of the disadvantages of non-aqueous titrations, this study shows an alternative aqueous acid-base titration method for quantification of SLC, using low concentrations of the nonionic surfactant Tween 80 as a solubilization agent.



EXPERIMENTAL

Materials

- SLC, Replek Farm Ltd, Skopje.
- Sodium hydroxide 0.1 M (VS), Fisher Chemical.
- Potassium hydrogen phthalate, RV, (100.00% ± 0.05%) Merck KGaA
- Tween 80 (p.a.), Sigma-Aldrich Germany
- Water HPLC grade (TKA-LAB)
- Mettler Toledo DL 50 potentiometric titrator, DG111-SC combined glass pH electrode, automatic burette (10 mL)
- Mettler Toledo analytical balance

Methods

Sample solution

160.0 mg drug substance was dissolved in 50 mL 1% (v/v) Tween 80 solution.

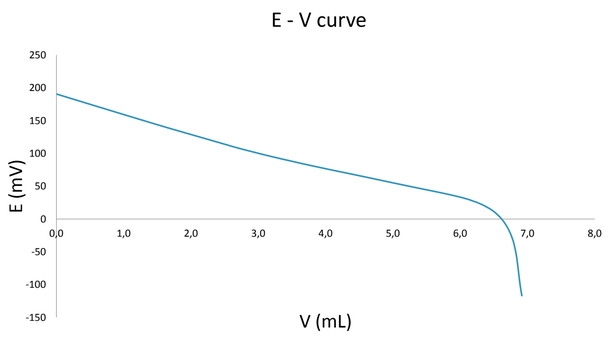
Titration

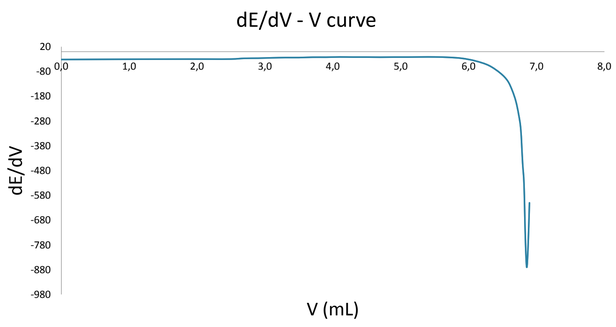
The sample solutions were titrated with 0.1 M NaOH VS, determining the end-point potentiometrically.

Calculation

1 mL of 0.1 M NaOH VS is equivalent to 22.22 mg sildenafil citrate.

RESULTS AND DISCUSSION





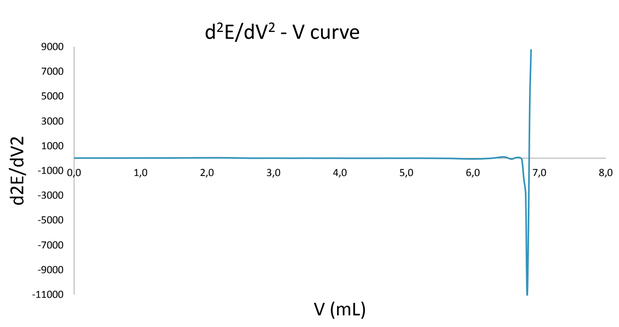


Table 1. Results from linear regression analysis

Parameter	Results
Regression equation	y = 45.743x – 0.0207
Coefficient of determination (R^2)	0.9999
Slope (b_{obs}) ± standard error	45.743 ± 0.19
Intercept (a_{obs}) ± standard error	- 0.0207 ±0.01

Table 2. Results from validation of method

Parameter	Limit	Result
Proportional systematic error (bias)	< 0.3 %	0.24 %
Additional systematic error (bias)	< 0.4 %	0.29 %
Precision (statistical error)	< 0.3 %	0.21 %
Practical relative error	< 0.67 %	0.53%
Relative standard deviation (n=6)	< 0.5 %	0.2 %

Table 3. Content of sildenafil citrate

Sample	V (NaOH)	Content of Sildenafil citrate (%)
1	6.69	100.5
2	6.58	100.8
3	6.58	100.7
	Average	100.6
	SD	0.171
	RSD/%	0.17

CONCLUSION

The proposed potentiometric method presents an inexpensive, fast and simple method for quantitative determination of SLC. This eco-friendly method could be a suitable alternative to sophisticated and time-consuming instrumental methods such as HPLC and could be easily employed in the quality control of this active substance. Results indicate that use of Tween 80 in low concentrations as a solubilization agent, could potentially be a replacement for the non-aqueous titrations.

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