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RESEARCH ARTICLE

# UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT FOR THE DETERMINATION OF DESVENLAFAXINE SUCCINATE IN TABLET FORMULATION

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**Desvenlafaxine succinate is a synthetic form of the major active metabolite of venlafaxine. The aim of the present study was to develop a simple, accurate, precise and reproducible method for the estimation of desvenlafaxine succinate in tablet dosage form using UV spectrophotometry. Purified water was used as the solvent for desvenlafaxine succinate. The UV spectrum of desvenlafaxine in water showed $\lambda_{max}$ at 224 nm and Beer-Lambert law was obeyed in the concentration range of 5-40 $\mu$g/ml. The result of analysis has been validated statistically. The recovery studies range from 99.78±1.05%, confirmed the accuracy of the proposed methods. The method was found to be precise with % relative standard deviation ±(0.244%) for interday precision and for intraday ±(0.243%). The proposed method is simple, precise, accurate and rapid for the determination of desvenlafaxine succinate in tablet dosage forms.**

**Key words:** Desvenlafaxine succinate, UV spectrophotometry, Tablet dosage form, Beer-Lambet law.

## INTRODUCTION

Desvenlafaxine succinate is an antidepressant of the serotonin-nor epinephrine reuptake inhibitor class. Desvenlafaxine is a synthetic form of the isolated major active metabolite of venlafaxine, and is categorized as a serotonin-nor epinephrine reuptake inhibitor (SNRI). It works by blocking the transporter "reuptake" proteins for key neurotransmitters affecting mood, thereby leaving more active neurotransmitters in the synapse. The neurotransmitters affected are serotonin (5-hydroxytryptamine) and nor epinephrine (noradrenalin). It is approximately 10-fold more potent at inhibiting serotonin uptake than nor epinephrine uptake. When most normal metabolizers take venlafaxine, 70% of the benefit comes from venlafaxine being metabolized into desvenlafaxine, so the effects are very similar. It is being targeted as the major depressive disorder, vasomotor symptoms associated with menopause, fibromyalgia and diabetic neuropathy. Chemically, it is 4-[2-Dimethylamino)-1-(1-hydroxycyclohexyl) ethyl] phenol succinate hydrate. The literature review revealed that no method is yet reported for the UV spectrophotometric estimation of the desvenlafaxine succinate in tablet dosage forms. The present study describes a simple, rapid, accurate and reproducible method for the estimation of desvenlafaxine succinate in tablet formulations.

## MATERIALS AND METHODS

### *Instrument*

Perkin-Elmer UV-Visible spectrophotometer was used for spectral measurements with spectral band width 1 nm, wavelength accuracy 0.5 nm and 1 cm matched quartz cells.

***Analytical procedure***

Standard stock solution (100 µg/ml) of the desvenlafaxine succinate was prepared by dissolving 10 mg of pure desvenlafaxine succinate in 100 ml water and aliquot of this solution was further diluted to get concentration of 20 µg/ml. (Beckett and Stenlake, 1997; Connors, 1999; Chatwal and Anand, 2009; Sharma, 2007; Skoog *et al* 2008). This solution was then scanned in the wavelength range of 200-400 nm. The wavelength selected for the analysis of desvenlafaxine succinate was 224 nm as absorption maxima was observed at this wavelength (**Figure 1**). Desvenlafaxine succinate showed linearity with absorbance in the range of 5-40 µg/ml (**Figure 2**). Coefficient of correlation was found to be 0.998 (**Table 1**). Absorbance value of desvenlafaxine succinate was found to be 238 and results of absorptivity values of drugs are shown in **Table 2**.

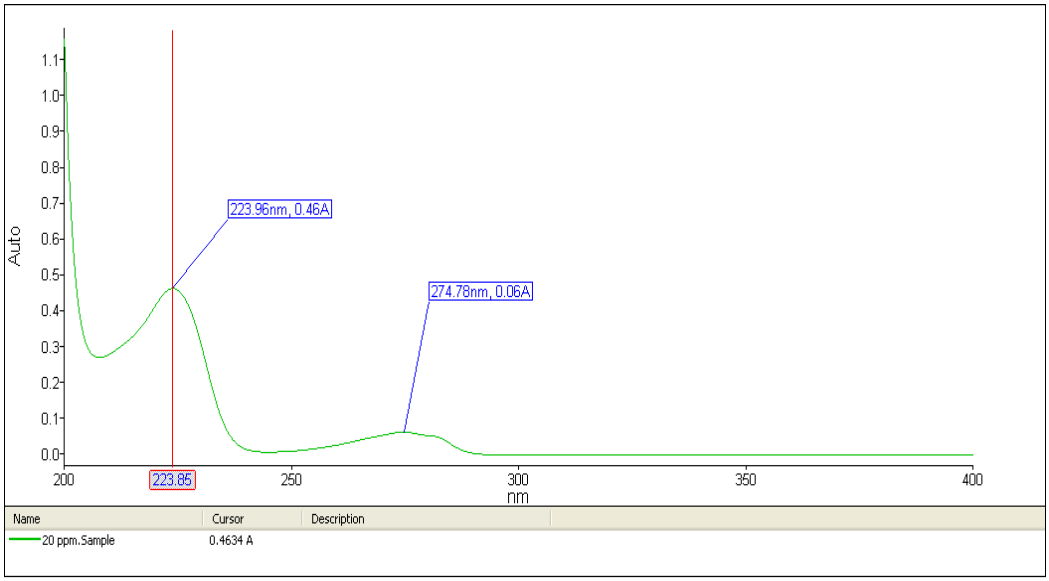


**Figure 1.** UV Spectrum of desvenlafaxine succinate in purified water

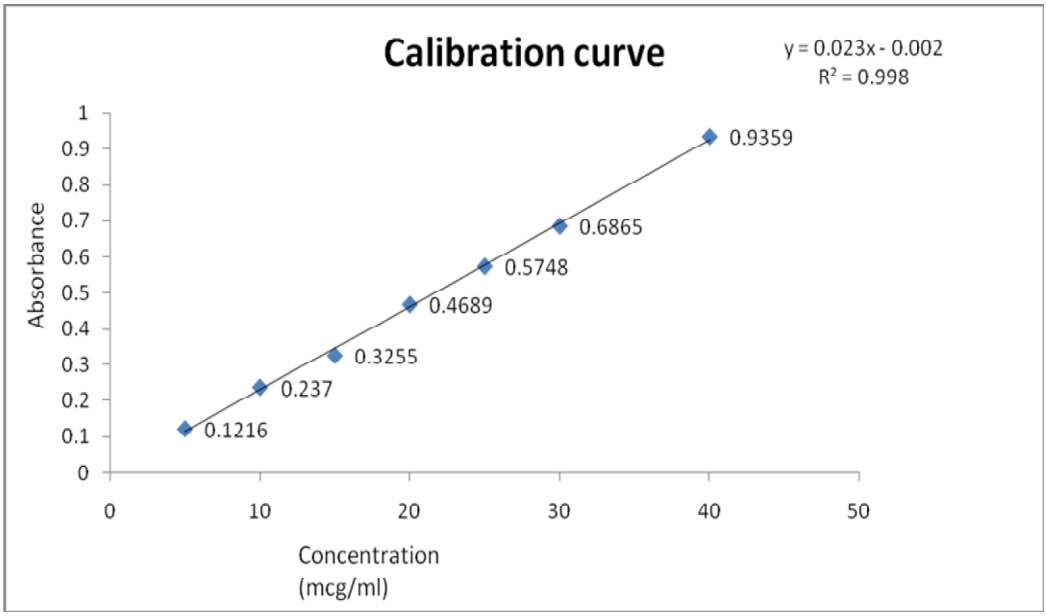


**Figure 2.** Calibration curve of desvenlafaxine succinate in purified water

**Table 1.** Regression and optical characteristics of desvenlafaxine succinate

| S. No. | Parameters | Results |
|---|---|---|
| 1 | Selected analytical wavelength | 224 nm |
| 2 | Beer's law range | 5-40 $\mu$g/ml |
| 3 | Coefficient of correlation | 0.998 |
| 4 | Slope | 0.023 |
| 5 | Intercept | 0.002 |

**Table 2.** Determination of A (1%, 1cm) of desvenlafaxine succinate

| Sr. No. | Absorbance | A (1%, 1cm) | Molar absorptivity |
|---|---|---|---|
| 1 | 0.476 | 238.0 | 9507.62 |
| 2 | 0.492 | 246.0 | 9827.21 |
| 3 | 0.468 | 234.0 | 9347.83 |
| 4 | 0.475 | 237.5 | 9487.65 |
| 5 | 0.474 | 237.0 | 9467.68 |
| 6 | 0.471 | 235.5 | 9407.75 |
| **Average** | **0.476±0.008** | **238.0±4.18** | **9507.62** |

***Analysis of tablet formulation***

In order to see the feasibility of proposed method for estimation of desvenlafaxine succinate in marketed pharmaceutical formulations for analysis of commercial formulation, twenty tablets were weighed, their average weight was determined and finally crushed into fine powder. A quantity of tablet powder equivalent to 10 mg of desvenlafaxine succinate was transferred into 100 ml glass volumetric flask containing 50 ml water, shaken manually for 10 min, volume was adjusted to mark with same solvent and filtered through whatman filter paper no. 41. The appropriate aliquots were transferred to 10 ml glass volumetric flask and volume was adjusted to the mark with same solvent to obtain concentration of 20 $\mu$g/ml. The absorbances of the solutions were recorded at 224 nm and the concentration of the desvenlafaxine succinate was determined. % label claim was then calculated and the results obtained are tabulated in **Table 3**.

**Table 3.** Results of analysis of tablets

| Sr. No. | Sample | Statistical data | % Label claim |
|---|---|---|---|
| 1. | Tablet | Mean | 100.13% |

***Validation***

Recovery studies were performed by adding a known amount of standard drug (80%, 100% and 120%) to pre-analyzed sample and contents were reanalyzed by proposed method. The other validation parameter like precision (interday, intraday) were also studied (ICH Q2B). The results of validation studies for estimation of desvenlafaxine succinate are presented in **Table 4**.

**Table 4.** Validation studies

| S. No. | Parameters | Results |
|---|---|---|
| 1. | Mean % recovery | 99.78 ± 1.05% |
| 2. | Precision (as % relative standard deviation) | |
| | Interday Precision | 0.244% |
| | Intraday Precision | 0.243% |

## RESULT AND DISCUSSION

The method developed for spectrophotometric determination of desvenlafaxine succinate in tablet formulation was found to be simple and convenient for the routine analysis. Beer-Lambert's law was obeyed in the concentration range of 5-40 $\mu$g/ml. Coefficient of variation was found to be 0.998. The percentage recoveries were found in the range of 99.78±1.05%. The method was found to be precise with % relative standard deviation ±(0.244%) for the interday precision and ±(0.243%) for intraday.

## CONCLUSION

The proposed method is simple, precise, accurate and rapid for the determination of desvenlafaxine succinate in tablet dosage forms. Analysis of authentic samples containing desvenlafaxine succinate showed no interference from common additives and excipients. Hence, recommended procedure is well suited for assay and evaluation of drugs in pharmaceutical preparations. It can be easily and conveniently adopted for routine quality control analysis.

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Validation of Analytical Procedures, Text and Methodology (Q2B), ICH Harmonized Tripartite Guideline.

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