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Short communication

Validation and comparison of UV spectrophotometry and HPLC methods for the determination of dissolution rate of Venlafaxine in Zanfexa 37.5mg tablets

Magdalena Atanasovski*, Sanja Hristovska, Stevche Petrovski, Gordana Mitrovska Evgenievska, Marija Stojanovska, Hristina Babunovska

Alkaloid AD, Blvd. Aleksandar Makedonski 12, 1000, Skopje, Republic of North Macedonia

Introduction

Venlafaxine is used to treat depression. It may improve your mood and energy level, and may help restore your interest in daily living. Venlafaxine is known as a serotonin-norepinerphine reuptake inhibitor (SNRI). It works by helping to restore the balance of certain natural substances (serotonin and norepinerphine) in the brain (WebMD).

UV spectrophotometric and new high performance liquid chromatography (HPLC) methods were developed for determination of dissolution rate of Venlafaxine in the tablet dosage form. A typical HPLC method was optimized in order to achieve better sensitivity, and robust, rapid, simple and accurate analysis (Nidadavolu, 2014).

Materials and Methods

Conditions for performing the dissolution test

For both methods are used the same medium and conditions for performing the dissolution test.

For analysis were used medium: 900 mL + 1% water, previously degassed, time: 30 minutes + 2%, speed: 100 rpm + 4% , temperature of medium :37 ± 0.5°C Apparatus 2 with paddle for dissolution test (BP/cPh Eur.2.9.3./USP<711>).

Results and discussion

The UV spectrum recorded between 200 nm and 400 nm using water as solvent and the wavelength 274 nm was selected for the determination of venlafaxine.

HPLC system equipped with an UV detector with variable wavelength was used and the wavelength 226nm was selected for the determination of venlafaxine. HPLC analysis was carried out using Inertsil ODS 3-C18, 250 mm x 4.6 mm, 5µm column and mobile phase composed of water, acetonitrile and triethylamine pH adjusted to 3.5 with orthophosphoric acid at a flow rate of 1.2 mL/min. Parameters such as linearity, precision, accuracy, recovery, specificity and robustness are studied as reported in the International Conference on Harmonization (ICH) guidelines (ICH Guideline Q2(R1), 2005).

UV spectrophotometry method

The specificity is demonstrated by comparison of the spectra of diluent, placebo solution, standard solution and sample solutions. There is no interference from diluent and placebo.

Linearity is determinate by series of three measurements of standards at five different concentrations that span 50 - 150% of the expected working range assayed. Linear correlations were obtained between the absorbance of Venlafaxine related to the concentrations of standards over the range of 0.0208 - 0.0625 mg/mL.

The accuracy of the method was determined by interaction studies for constant placebo of the tablets′ concentration level, but varying Venlafaxine

*msazdova@alkaloid.com.mk

hydrochloride concentrations. The samples were prepared in three concentration levels. Venlafaxine content was determined in each sample by spectrophotometric method and with the obtained results a statistic determination was performed. The recovery results indicate that the test method has an acceptable level of accuracy.

The precision of the method was verified by repeatability and intermediate precision. The system repeatability was shown by six measurements of the absorbance of the standard solution in concentration of 0.0417 mg/mL. The relative standard deviation of the absorbance's obtained by 6 replicate measurements was 0.24%.

New HPLC method

From the diluent and placebo chromatogram, it was concluded that no peaks were observed at retention time of the active ingredient Venlafaxine. Hence, it can be concluded that there is no interference due to diluent and placebo for the determination of dissolution rate of Venlafaxine.

Linearity is determinate by series of injections of standards at six different concentrations that span 50 - 150% of the working concentration. Linear correlations were obtained between the responses of Venlafaxine peak related to the concentrations of standards over the range of 0.02 – 0.13 mg/mL. Response is linear over the concentration range from 50 to 150% of the working concentration.

For Accuracy known amount of placebo at 100% concentration was taken separately into different dissolution vessel and spiked with known quantities of Venlafaxine at three different levels, in triplicate. The samples were analyzed by the proposed method and the amount of Venlafaxine recovered was calculated. The recovery results indicate that the test method has an acceptable level of accuracy.

Analytical procedure was used within the same laboratory over a short time, performed by two different analysts on the same equipment. The analysis was performed by two different analysts on different equipment and on different days. It is determinated that the method is precise.

The precision of the method was verified by repeatability, method precision and intermediate precision. The repeatability of the chromatographic systems was shown by six replicate injections of the standard solution of Venlafaxine in concentration of 41.65 µg/mL.

The method precision was demonstrated by preparation of six sample solutions using single batch of tablets as per test method.

For verification of intermediate precision were prepared six sample solutions individually using single batch of tablets as per test method. The analysis was performed by two different analysts on different equipment and on different days. It was determinated that the method is precise.

Robustness of the method was measured by making small, deliberate changes to the chromatographic conditions and observing the effect of these changes on the system suitability parameters (flow rate, mobile phase composition, column temperature, column batch, non-degassed and degassed medium). It can be concluded that the test method is robust for all the varied conditions.

Conclusion

All these results have shown that there is no significant difference in Spectrophotometric and HPLC determination of dissolution rate of Venlafaxine in Zanfexa 37.5mg tablets. Both methods are sensitive, accurate, precise and useful for the determination of Venlafaxine in tablets and they can be used for Quality Control analysis.

References

ICH Guideline Q2(R1): "Validation of Analytical procedures: Text and Methodology", November 2005.

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