A VALIDATED SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF VILAZODONE HYDROCHLORIDE IN PHARMACEUTICAL DOSAGE FORM

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Abstract

Objective: In the present research work three simple, accurate, precise methods of the UV-visible spectrophotometric method was developed and validated for the estimation of Vilazodone HCl in bulk and tablet dosage. Methods: Three methods were used for estimation of Vilazodone HCl using methanol. Method A involves zero order spectroscopy at absorption maximum of 241 nm; Method B involves first order derivative at 246.5 nm and Method C involves second-order derivative at 243.5 nm. The developed methods were validated according to ICH guidelines. Results: The developed methods were found to be linear in the concentration range of 1-5 µg/ml. The mean percentage label claim of Vilazodone HCl was within the acceptable range. The accuracy data showed % recovery and % RSD within the range. Conclusion: The developed methods were found to be accurate and precise. The % RSD values were within limits. These methods can be used for the routine analysis of Vilazodone HCl in bulk and tablet dosage form.

A VALIDATED SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF SAROGLITAZAR IN PHARMACEUTICAL DOSAGE FORM

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Abstract

In the present research work two simple, accurate, precise methods of UV-visible spectrophotometric method was developed and validated for the estimation of Saroglitazar in phamaceutical dosage form. Two methods were used for estimation of Saroglitazar using methanol. Method A involves zero order spectroscopy at absorption maximum of 295 nm and Method B involves first order derivative at 319 nm. Overlay linearity graph were taken using different concentration of Saroglitazar. The developed methods were validated according to ICH guidelines. The developed methods were found to be linear in concentration range of 5-30 μg/ml with regression equation Y = 0.028x + 0.007. The mean percentage label claim of Saroglitazar was within the acceptable range. The recovery of the drug was ranged between 99.28-101.58%. The developed methods were found to be accurate and precise. The % RSD values were within the limits. These methods can be used for the routine analysis of Saroglitazar in pharmaceutical dosage form.

METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF SAROGLITAZAR IN PHARMACEUTICAL DOSAGE FORM BY RP-HPLC

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Abstract

A simple, sensitive and rapid reverse phase high performance liquid chromatographic method was developed for the estimation of Saroglitazar in tablet dosage form. A C18 Inertsil ODS column (250 × 4.6 mm, 5 µm particle size) was used as a stationary phase with a mobile phase containing a mixture of phosphate buffer and acetonitrile in the ratio of 40:60, v/v. The flow rate was 1.0 mL/min. The effluent was monitored at 294 nm and eluted at 2.162 min. Calibration curve was plotted with a range from 20-100 µg/ml for Saroglitazar and the correlation was found to be 0.999. The accuracy range was found between 99.95 -101.07%. The % RSD values for both intraday and interday precision were less than 2.0. The limit of detection (LOD) and limit of quantification (LOQ) were found to be 1.405 µg/ml and 4.260 µg/ml respectively. The assay was validated for the parameters like system suitability, precision, accuracy, and robustness parameters. The proposed method can be useful for the routine determination of Saroglitazar in pharmaceutical dosage form.

METHOD DEVELOPMENT AND VALIDATION OF TENELIGLIPTIN IN PHARMACEUTICAL DOSAGE FORM BY UV SPECTROPHOTOMETRIC METHODS

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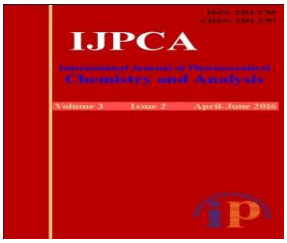

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Abstract

Teneligliptin was estimated in tablet form by ultraviolet-spectrophotometric methods followed by distilled water as solvent. Here three methods were used for quantitative estimation of teneligliptin in tablet dosage form. Quantitative estimation of pure drug solution was done at λmax of 244 nm for method I. For measurement of response in method II peak minima of 266.4 nm was selected. Wavelength range of 238.6-247.8 nm was selected for calculating area in area under the curve method. Validation of the methods was performed according to guidelines of International Conference on Harmonisation. The % assay of the formulation by the three methods was in the range of 100.17-100.74. Graph was linear in the range of 5-70 µg/mL for zero order and AUC techniques, while 5-80 µg/mL for first order derivative technique. Good correlation between response and concentration was found as the value of regression coefficient (R2) was 0.999. The accuracy of the drug was ranged in between 98.54-101.80 for all ultraviolet-spectrophotometric methods and was in acceptable range. The percentage RSD values for method precision for all the methods were within the limit of ≤ 2. From the data it was concluded that the methods developed have scope to be applied for quantitative estimation of pure drug of teneligliptin in pharmaceutical dosage form.