Abstract

ABSTRACT

In the present work, four simple, sensitive and specific RP-HPLC methods have been developed for the quantitative estimation of Orlistat, Gliclazide, Dapagliflozin and Alogliptin in bulk and pharmaceutical formulation. A simple, specific, accurate, and precise reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the estimation of Orlistat in pharmaceutical dosage forms. The chromatographic separation of Orlistat was achieved on a Symmetry C\textsubscript{18} Column with 250mmx4.6mm i.d, 5µm particle size, using UV detection at 215nm. The optimized mobile phase was consisted of Acetonitrile: Phosphate buffer pH adjusted to 2.9 with Orthophosphoric acid (60:40v/v). The flow rate was 1ml/min and effluents were monitored at 215 nm. Chromatogram showed the main peak at a retention time of 4.765min. The method was validated for linearity, accuracy, precision, and limit of detection, limit of quantification, robustness and ruggedness. The linearity was found in the concentration range of 20-70µg/ml. The Correlation coefficient was 0.999. The regression equation was found to be $Y = 28286x+15416$. The limit of detection and limit of quantification for estimation of Orlistat was found to be 0.73µg/ml and 2.19µg/ml respectively. Recovery of Orlistat was found to be in the range of 99.73-100.07%. Proposed method was successfully applied for the quantitative determination of Orlistat in pharmaceutical dosage form.

A simple, sensitive and specific RP-HPLC method has been developed for the quantitative estimation of Gliclazide in bulk and pharmaceutical formulation. A simple, specific, accurate, and precise reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the estimation of Gliclazide in pharmaceutical dosage forms. The chromatographic separation of Gliclazide was achieved on a Develosil ODS HG-5(C\textsubscript{18}) RP Column, 150mm x 4.6 mm. i.d. 5µm particle size, using UV detection at 224nm. The optimized mobile phase was consisted of Acetonitrile: Phosphate buffer pH adjusted to 2.8 with Orthophosphoric acid (70:30 v/v). The flow rate was 1ml/min and effluents were monitored at 224 nm. Chromatogram showed the main peak at a retention time of 3.745min. The method was validated for linearity, accuracy, precision, and limit of detection, limit of quantification, robustness and ruggedness. The linearity was found in the concentration range of 20-70µg/ml. The Correlation coefficient was 0.999. The regression equation was found to be $Y = 89983x+672.7$. The limit of detection and limit of quantification for estimation of Gliclazide was found to be 0.8µg/ml and 2.5µg/ml respectively. Recovery of Gliclazide was found to be in the range of 99.8-
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100.01%. Proposed method was successfully applied for the quantitative determination of Gliclazide in pharmaceutical dosage form.

A simple, sensitive and specific RP-HPLC method has been developed for the quantitative estimation of Dapagliflozin in bulk and pharmaceutical formulation. A simple, specific, accurate, and precise reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the estimation of Dapagliflozin in pharmaceutical dosage forms. The chromatographic separation of Dapagliflozin was achieved on a Symmetry C18, 250mmx4.6mm i.d, 5\(\mu\)m Particle size, using UV detection at 246nm. The optimized mobile phase was consisted of Methanol: Acetonitrile: 1\% OPA in the ratio of (75:20:05 v/v/v). The flow rate was 1ml/min and effluents were monitored at 246 nm. Chromatogram showed the main peak at a retention time of 2.797min. The method was validated for linearity, accuracy, precision, and limit of detection, limit of quantification, robustness and ruggedness. The linearity was found in the concentration range of 20-70\(\mu\)g/ml. The Correlation coefficient was 0.999. The regression equation was found to be \(Y = 2423x+1255\). The limit of detection and limit of quantification for estimation of Dapagliflozin was found to be 0.04\(\mu\)g/ml and 0.12\(\mu\)g/ml respectively. Recovery of Dapagliflozin was found to be in the range of 99.96-100.53\%. Proposed method was successfully applied for the quantitative determination of Dapagliflozin in pharmaceutical dosage form.

A simple, sensitive and specific RP-HPLC method has been developed for the quantitative estimation of Alogliptin in bulk and pharmaceutical formulation. A simple, specific, accurate, and precise reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the estimation of Alogliptin in pharmaceutical dosage forms. The chromatographic separation of Alogliptin was achieved on a Symmetry C18, 250mmx4.6mm i.d, 5\(\mu\)m Particle size, using UV detection at 236nm. The optimized mobile phase was consisted of Methanol: Phosphate Buffer (pH adjusted to 3.2 with Glacial acetic acid) in the ratio of (65:35 v/v). The flow rate was 1ml/min and effluents were monitored at 236 nm. Chromatogram showed the main peak at a retention time of 3.447min. The method was validated for linearity, accuracy, precision, and limit of detection, limit of quantification, robustness and ruggedness. The linearity was found in the concentration range of 6-16\(\mu\)g/ml. The Correlation coefficient was 0.999. The regression equation was found to be \(Y = 49789x+2994\). The limit of detection and limit of quantification for estimation of Alogliptin was found to be 0.09\(\mu\)g/ml and 0.27\(\mu\)g/ml respectively. Recovery
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of Alogliptin was found to be in the range of 99.97-100.64%. Proposed method was successfully applied for the quantitative determination of Alogliptin in pharmaceutical dosage form.

Key words:
Orlistat, Gliclazide, Dapagliflozin, Alogliptin, UV detection and RP-HPLC.