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Analytical method development and validation for the determination of sitagliptin and metformin using rp-hplc method in bulk and tablet dosage form

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A new simple, sensitive, accurate, precise and reproducible RP-HPLC method has been developed for the simultaneous estimation of sitagliptin and metformin in bulk and pharmaceutical dosage form using C 18 column (waters, 250 X 4.6 mm, 5µm) in isocratic mode. The mobile phase consisted of 0.1 M Dipotassium phosphate buffer (pH 7) and acetonitrile in the ratio of 70:30 v/v. The detection was carried out at 223 nm for sitagliptin and 316 nm for metformin. The method was linear over the concentration range for Sitagliptin 100-300 µg/ml and for Metformin 200-600 µg/ml. The recoveries of sitagliptin and metformin were found to be 100.27 and 100.73% respectively. The validation of Method was carried out utilizing ICH-guidelines. The described HPLC Method was successfully employed for the analysis of pharmaceutical formulations containing combined dosage form.

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