An Innovative Method For Estimation Of Metformin HCl and Acarbose in Pharmaceutical Products and Seperation of Metformin Impurities By RP-HPLC

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Abstract : A Simple, rapid, cost effective, stability indicating RP-HPLC method has been developed for separation of Metformin HCl, its related impurities and Acarbose. Validated the method for simultaneous estimation of Metformin (MF) and Acarbose (ACB) in its novel combination of tablet formulation with Metformin 500 mg and Acarbose 50 mg. Metformin HCl is an orally-administered biguanide, anti-hyperglycemic agent, used in the management of non-insulin dependent diabetes mellitus. Acarbose is an oligosaccharide, used orally for the treatment of type 2 diabetes mellitus. The separation was achieved by using isocratic mobile phase consisting of mixture of phosphate buffer : acetonitrile (27:73 v/v), using Hypersil APS-2 column, (250 x 4.6 mm x 5μm) column at flow rate 2.0 mL/min. The detection was carried out at 210 nm with 20 μl of injection volume. The column temperature was maintained at 35 °C. The retention time (RT) of MF, its related impurities and ACB were found to be RT 2.6 min for 1-Cynogaunidine (RC A), 6.0 for Metformin (MF), 8.5 for 1-Methylbigaunidine (RC B), 10.4 for N,N-Dimethyl-1,3,5-triazine-2,4,6-triamine(RC C), and 12.2 min for Acarbose (ACB). The approach was found to be linear with the concentration of 5-25 μg/ml and 2.5-15μg/ml and correlation coefficient was 0.999 for MF and ACB respectively. The assay of estimated compounds was found to be 99.19% and 99.08% w/v and mean accuracy 100.66%, 101.59% for MF and ACB respectively. The developed method was validated as per ICH guidelines. The degradation products were well resolved from main peak. The validation was performed for various parameters like specificity, linearity, precision, accuracy and robustness studies. The method was found to be capable for simultaneous quantification of Metformin and Acarbose in its combination drug.

Key words : Metformin HCl, 1-Cynogaunidine, 1-Methylbigaunidine, N,N-Dimethyl-1,3,5-triazine-2,4,6-triamine, Acarbose, development, Degradation, Validation, USP, ICH guidelines.

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