DEVELOPMENT AND VALIDATION OF RP-HPLC FOR SIMULTANEOUS QUANTITATION OF LINAGLIPTIN, DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE AND METFORMIN HYDROCHLORIDE: GREENNESS EVALUATION BY AGREE AND GAPI TOOLS

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ABSTRACT

A reverse phase high performance liquid chromatography (RP-HPLC) method has been developed and validated as a precise, accurate and cost-effective approach for the concurrent quantification of dapagliflozin propanediol monohydrate (DAPA), linagliptin (LINA) and metformin hydrochloride (METF). The greenness of the current approach was assessed using AGREE and GAPI tools. The Agilent Eclipse XBD C18 column (5 µm, 150 × 4.5 mm) and eluent consisting of buffer (pH adjusted to 3) and methanol (40:60 V/V) in isocratic condition, at 1.0 mL min^{-1} was finalized. The drugs were monitored at 215 nm. Linearity was attained encompassing the concentration range 2.5 - 7.5 µg mL^{-1}, 1.25 - 3.75 µg mL^{-1} and 125 - 375 µg mL^{-1} for DAPA, LINA and METF, respectively. The precision results were within the acceptable limit of % relative standard deviation (% RSD) i.e. less than 2, and % recovery outcomes were found to be within the limit. This technique can be used routinely to quantify simultaneously METF, LINA and DAPA, in quality control laboratories. The developed method is environmental and operator-friendly.