ABSTRACT

Development and Validation of Ultra Fast Liquid Chromatography Method for a Dissolution Test of Glimepiride and Metformin Tablet

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A rapid, specific and reproducible ultra fast liquid chromatographic method was developed and validated for simultaneous estimation of glimepiride and metformin release in tablet dosage form. Analysis was performed on Shimadzu LC-Nexera, Phenomenex Luna C_8 (50 mm x 2.00 mm, 3µm) column with mobile phase consisting of acetonitrile and pentanesulfonic acid sodium salt, glacial acetic acid solution with gradient mode. The flow rate was 0.5 ml/min column maintained at 40°C and the injection volume of 10µl. UV detection was set at 228nm and 253nm. The selected chromatographic condition was found to effectively separate glimepiride and metformin with retention time of 5.7 and 1.3 min, respectively. The dissolution conditions include the USP apparatus 2 at a paddle rotation rate of 75 rpm and 900 mL of phosphate buffer (pH 7.8) as dissolution medium, at 37 ± 0.5°C. The method was validated for specificity, linearity, accuracy, precision and filtration effect. Linearity calibration curve showed linear response over the range of 0.44-2.65 ppm and 111.09-666.40 ppm for glimepiride and metformin, respectively. Average recovery of glimepiride was 97.24% and 99.80% for metformin, whilst precision (%RSD) of glimepiride was 1.298% and 0.388% for metformin. The result met the requirements and the method can be used for dissolution test of these drugs.

Keyword: liquid chromatography, dissolution, method validation, glimepiride, metformin