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Bioanalytical method development, validation and pharmacokinetics study of 5-fluorouracil loaded nanoparticles

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Background: 5-fluorouracil (5FU) is a chemotherapeutic agent against different types of cancer. 5FU loaded with nanotechnology can enhance efficacy over conventional drawback of 5-FU, such as short half-life, toxicity, low bioavailability and non-selective action. Pharmacokinetic profile of this advanced nano-formulation is needed to correlate with overall ADME (absorption, distribution, metabolism and excretion) process.

Aim: The purpose of this study is to develop HPLC-UV method and validate the performance in expression of specificity, precision, sensitivity, accuracy and stability of the developed 5-fluorouracil nanoparticles (5-FUNPs) and to correlate and collect the valuable pharmacokinetics data.

Methodology: 5-FUNPs were formulated with polymer poly lactic co-glycolic acid with oil-in-water/solvent evaporation. Characterizations of nanoformulation was performed which included particle size and stability studies. Analytical method was developed and validated from HPLC-UV and was applied to pharmacokinetic parameters.

Results: The calibration curve plotted for 5-FUNPs was linear at 267 nm. The lower limit for the quantification was found 10.13 ng/mL. The size of 5-FUNPs was between 137 ± 0.97 to 193 ± 0.93 nm and zeta potential between 0.27 ± 0.08 to 0.29 ± 0.07 mv on the side of positively charged. The highest peak for drug concentration, C_{max} was 3.235 ± 0.78 mg/L at highest time point, T_{max} 7.21 ± 2.52 hours. The AUC(0-96) and AUC(0- ∞) showed 8.89 ± 4.98 mg/L-h and 9.57 ± 3.77 mg/L-h respectively and $t_{1/2}$ was 22.98 ± 3.73 hours.

Conclusion: The results showed a simple, specific, sensitive and stable HPLC-UV method for the quantitative determination of 5-FUNPs in plasma and successfully applied to the pharmacokinetic study after oral administration in rats.

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