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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 correlates with overall ADME (absorption, distribution, metabolism and excretion) process.

**Purpose:** The purpose of this study is to develop HPLC-UV method and validate its performance in expression of specificity, precision, sensitivity, accuracy and stability of the developed 5-fluorouracil nanoparticles (5-FUNPs) and 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 were performed which included particle size and stability studies. Analytical method was developed and validated from HPLC-UV and 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 hrs. The AUC<sub>(0-96)</sub> & AUC<sub>(0-96)</sub> showed 8.89±4.98 mg/L-h and 9.57±3.77 mg/L-h respectively and t1/2 was 22.98±3.73 hrs.

**Conclusion:** The results show 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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