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Selection of best calibration model during bioanalytical method validation

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The quality of bioanalytical data is highly dependent on using an appropriate regression model. The most common and simplest approach to fit a calibration curve to data points (x, y) is by ordinary linear regression and to express the correlation coefficient (r2) to define the degree of association between these two variables with the acceptable value greater than 0.99. However, r2 alone is not adequate to demonstrate linearity, as the ordinary linear regression approach presupposes that each data point in the selected range has a constant absolute variable (i.e. homoscedasticity). But most of the bioanalytical assays usually have to cover a broad concentration range and the variance is more likely to increase with concentration (i.e. heteroscedasticity) which finally impairs accuracy despite of acceptable r2 value. An alternative approach is to use the weighted linear regression which normally generates a better curve fit than ordinary linear regression and increases accuracy over the whole concentration range. So there is a need to study and suggest an approach in selection of a calibration model during bioanalytical method validation which offers degree of assurance that the developed method will hold true during routine use.

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Development of 5-fluorouracil enteric -coated nanoparticles for sustained and localized release and their in vitro characterization for treatment of colorectal cancer

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5-Fluorouracil is used in the treatment of colorectal cancer along with oxaliplatin as first line treatment, but it is still having lack of site specificity and poor therapeutic effect. Apart from that it exhibits toxic effects to healthy cells and decrease the drug availability at colon region. These limitations were overcome by formulating them as enteric- coated chitosan polymeric nanoparticles as drug can be delivered directly to large bowel. The main reason for opting for enteric coating is due to its protection of drug at gastric pH. So the main objective was to prepare polymeric nanoparticles using chitosan with different ratios of polymer (1:1, 1:2, 1:3, 1:4) by solvent evaporation emulsification method. It was then characterized by differential scanning calorimetry (DSC), X-ray diffraction (XRD), entrapment efficiency and particle size and further subjected to enteric coating. Dialysis bag technique was selected to determine drug in vitro release using various simulated fluids with pH (1.2, 4.5, 7.5, 7.0) to mimic the GIT tract. 5-FU nanoparticles with drug: polymer ratio of 1:2 and 1:3 has shown better particle size (149±1.28 nm and 138±1.01 nm respectively), entrapment efficiency (48.12±0.08% and 69.18±1.89 respectively). Comparative approach with non-enteric coated tablets shows a better drug release for 5-FU E1 after 4 h (initial burst release) followed by sustained release of 82% till 24 h, where as non enteric coated tablet released more than half the amount of the drug before reaching the colon area. So, these results conclude the usage of prepared nanoparticles as a potential drug delivery approach for the treatment of colorectal tumors.

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