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Stability indicating RP-HPLC method for the estimation of decitabine in bulk drug and lipid based nanoparticles

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The aim of our present work was to develop and validate a reverse phase high-performance liquid chromatography (RP-HPLC) method for the determination of Decitabine (DCB). The developed method was further applied to observe the degradation of DCB under various stress conditions. Chromatographic separation was achieved on C18, 250×4.6 mm, particle size 5 µm, Agilent column, using ammonium acetate (0.01 M) as mobile phase with flow rate of 1 mL/min and injection volume was 20 µL. Quantification was carried out with UV detector at 230 nm with a linear calibration curve in the concentration range of 10-100 µg/mL based on peak area. Thus, developed method was validated for linearity, accuracy, precision, and robustness. Linearity was found to be in the range between 10-100 µg/mL with a significantly higher value of correlation coefficient $r^2=0.9994$. The limits of detection (LOD) and the limits of quantification (LOQ) were found to be 1.92 µg/mL and 5.82 µg/mL respectively. Moreover, validated method was applied to study the degradation profile of DCB under various stress degradation conditions. Examination of different stress conditions on degradation of DCB showed that its degradation was highly susceptible to oxidative condition as 31.24% of drug was degraded. In acidic and alkaline conditions, the drug was degraded by 21.03% and 12.16% respectively, while thermal and photolytic condition causes least degradation, i.e., 0.21% and 0.3% respectively. Finally, the proposed method was found to be sensitive, specific and was successfully applied for the estimation of DCB in bulk drug, and lipid based nanoparticles.

Biography

Kanchan Kohli completed her PhD from Hamdard University in 2001. She is currently working as an associate professor of the Faculty of Pharmacy of Hamdard University. Her research interests are Nanoparticulate drug delivery systems. She has more than 150 papers published in International Journals and authored more than 10 chapters of books. She has filled 6 Indian patents and one US patent.

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