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Quality by design (QbD)-based development and optimization of a simple, robust HPLC method for the estimation of Rifabutin

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Rifabutin with piperine is utilized for antitubercular therapy, where piperine is used as an immunomodulator. However, its estimation in different dosage forms is still a challenge. Though, various analytical methods have been reported, but they are tedious, difficult to reproduce, and time consuming. USP method is reliable only for rifabutin and piperine method development and validation, but suffers from disadvantage of having high buffer concentration leading to column blockage. Therefore, it is needed to develop a novel HPLC method to overcome this problem. A simple, fast, and robust HPLC analytical method was developed by employing quality by design (QbD) for the estimation of drug in different dosage forms. The HPLC method was successfully developed and validated according to International Conference of Harmonization (ICH) guidelines with respect to linearity, accuracy, precision, etc. Further, the method was applied for estimation of rifabutin with piperine in different dosage forms like tablet, injection, lipid nanocarriers, lipid polymer hybrid nanoparticles (LPHNPs) by using software "Minitab". Good recoveries of both drugs were obtained and all values were found to be within the acceptable range. The results showed that the developed HPLC method could be successfully utilized for identification and quantification of rifabutin with piperine in any dosage form, with high resolution, accuracy, and precision.

Biography

Gyanendra Singh is pursuing his PhD in Department of Pharmaceutics, IIT-BHU, Varanasi as a PhD Research Scholar. He has qualified the "Graduate Aptitude Test for Engineering", in (GATE-2004) and Graduate Pharmacy Aptitude Test, in (GPAT-2011). He has also awarded in "Pharmacy, Engineering and Technology Fellowship" for PhD in 2012 given by University Grant Commission, New Delhi. He has written a book on "*Niosomal Delivery on Antitubercular Drug*". He was awarded with "Gandhian Young Technological Innovation Award-2013" in the field of Pharmaceutics at Indian Institute of Management, (IIM), Ahmedabad, Gujarat, India. His area of interest is research in Novel Drug Delivery System.

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