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QbD approach for the development and optimization of HPLC method for the simultaneous estimation of four component cream formulation: Application to permeability study

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QbD based DOE approach was explored to study the effect of various factors influencing the optimisation of HPLC method for the simultaneous estimation of the four drugs viz. Ofloxacin (OFX), Ornidazole (ORN), Terbinafine Hydrochloride (TBH) and Clobetasol Propionate (CBP) in bulk drug and cream formulation. A full factorial design was employed to study the factors such as pH of the mobile phase, initial percentage of organic content for gradient elution (%BI) and gradient time (tG). The optimal conditions obtained after applying the principles of QbD with good system suitability parameters for all four drugs were found to be at pH 2.6, %BI as 24% of acetonitrile and gradient time of 4 min. The optimal conditions were found to be in a good agreement with the experimental results. The HPLC method thus developed was validated using ICH guidelines and was applied for the assay of cream formulation. The percentage recoveries were found to be 99.74±0.39 for OFX, 98.72±0.71 for ORN, 98.19±0.23 for TBH and 99.05±0.76 for CBP. The HPLC method was successfully applied to study the *in vitro* permeability of cream formulation in rat skin using Franz diffusion cell.

Biography

Prachi Bhamre is pursuing her PhD from Pharmacy Department, The Maharaja Sayajirao University of Baroda, Gujarat, India. She has completed three years of PhD and has worked on development of analytical methods including the areas such as QbD and chemometrics.

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