Development of Sensitive Spectrophotometric Method for Analysis of Darifenacin Hydrobromide Liposomes in Rat Plasma

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ABSTRACT:

A new simple and sensitive visible spectrophotometric method for the estimation of darifenacin hydrobromide (DHB) liposomes was developed using diazo coupling reagent, 3-amino phenol in spiked rat plasma. Spectrophotometric method was developed using diazo coupling reaction with the chromogenic reagent, 3-amino phenol for estimation of darifenacin hydrobromide in liposomes. 3-amino phenol forms a yellow colored diazo complex with darifenacin hydrobromide in acidic conditions. The color intensity range was found to be linear in the concentration range of 100-1000ng/mL. Analysis was carried out at its λmax 438nm. The method was validated according to ICH guidelines. The method was optimized and validated in spiked rat plasma according to USFDA guidelines. The developed method was simple and sensitive and the LOQ value was found to be 100ng/mL. All the validation parameters were found to be within the acceptable limits. As the method was sensitive, it was successfully applied to the analysis of darifenacin hydrobromide liposomes in spiked rat plasma.

KEYWORDS: 3-amino phenol, darifenacin hydrobromide, ICH guidelines and USFDA guidelines.