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Validation guidelines of hydralazine hydrochloride spectrophotometric method

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Spectrophotometric method was applied for the determination of hydralazine hydrochloride in pure and pharmaceutical tablet formulations. The method was validated for the elements postulated by the International Conference on Harmonization (ICH) guidelines Q2(R1) with respect to linearity and range, precision, accuracy, detection limit and quantitation limit. The method was based on a simple one-step method for the generation a yellow color ion-pair of hydralazinium ion and Bromophenol blue in acidic medium. The ion pair exhibits λmax at 416 nm and obeys Beer's Law in a linear range extended between 10-50 µg/mL. The detection limit and quantitation limit were found to be 0.82 and 0.27 µg/mL, respectively. The calculated molar absorptivity and Sandell's sensitivity are 1.01×10^4 L/mol.cm-1 and 0.0514 µg/mL, respectively. The method showed high recoveries equal to 98.94 and 99.5% for both pure and pharmaceutical formulations. In general, the method was found to be valid for the determination hydralazine hydrochloride and is expected to be useful in a variety of quality control pharmaceutical applications.

Biography

Laila A Al-Shatti has completed her PhD at 2009 from Kuwait University. She has published more than 13 papers in reputed journals and has been serving as an Assistant Professor in The Public Authority for Applied Education and Training.

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