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Determination of Saturated Ketoconazole Solubility Using Spectrophotometry Uv-Vis Method

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ABSTRACT

Ketoconazole is a weakly basic drug that has lower solubility at higher pH. Determination of solubility of ketoconazole in the base solution is not easy due to the poor solubility. The simple, low cost, efficient, accurate spectrophotometry methods in UV/VIS region have been developed for the determination of ketoconazole. The wavelengths were selected at 230 nm using solvent buffer phosphate pH 6.8. The Beers' law was obeyed in the concentration range 5-50 ppm. According to ICH guidelines the parameters such as linearity, accuracy, precision, the limit of detection, and the limit of quantification were studied. The regression equation of calibration curve was found to be y=0.0448x-0.13. All concentrations were linear, with the absorbance having a correlation coefficient 0.9994. The accuracy was found between 93.84-95.95%. The % Relative Standard Deviation (RSD) of Ketoconazole was found to be 0.112-1.237 for intraday and 0.008-0.792 for interday precision. The result of the limit of detection (LoD) for ketoconazole was 0.988 that could be reliably detected and the limit of quantification (LoQ) for ketoconazole was 3.294 ppm. The result of ketoconazole solubility was 21.044±0.759 ppm that indicating ketoconazole was a poorly soluble drug in the intestine. The proposed methods could be applied to the determination solublity ketoconazole in buffer phosphate pH 6.8 with good accuracy, good precise, and simple.

Keywords: UV spectrophotometry, ketoconazole, solubility ketoconazole, validation method