

Estimation and Validation of Sitagliptin by First Order Derivative Spectroscopy Method

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Abstract: A method has been successfully developed for the simultaneous estimation of Sitagliptin in both its bulk drug and tablet dosage form. The drug exhibits absorbance maxima at 228 nm in a 0.1N NaOH solution, and conforms to Beer's law within a concentration range of 10-50 µg/ml. The mean recovery rate for both the bulk drug and tablet form was determined to be 100%, indicating the method's efficacy in accurately retrieving the expected quantities of the drugs. Furthermore, the method demonstrated linearity close to 1, suggesting a strong correlation between concentration and absorbance, which is crucial for precise quantification. Assessment of precision through various parameters including intraday, interday, and intermediate precision, as well as robustness, yielded consistent results. The percentage recovery fell within the acceptable range of 82-138% for both drugs, further affirming the method's accuracy and reproducibility. Importantly, all validation parameters were found to be in compliance with the guidelines set forth by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ensuring the method's adherence to industry standards. In conclusion, these findings collectively underscore the accuracy, precision, and simplicity of the developed method for the simultaneous estimation of Sitagliptin bulk drug and its tablet dosage form.

Keywords: Sitagliptin, UV Spectroscopy, First derivative spectrophotometric, Spectrophotometric determination