

SPECTROPHOTOMETRIC ESTIMATION OF NERATINIB PHARMACEUTICALS: APPLICATIONS TO CHEMOMETRICS SUPPORTED ROBUSTNESS TESTING AND METHOD GREENNESS ASSESSMENT

Sagar S. Panda^{a*} and Suman K. Mekap^b

(Received 28 April 2022) (Accepted 27 October 2023)

ABSTRACT

Neratinib is a novel anti-breast cancer agent approved for treating the early stages of breast cancer in women. Based on the non-availability of methods, the authors developed two UV spectrophotometric methods using water as a solvent. The drug shows a maximum absorption of 263 nm in water. Further, the measurement of the area under the curve within 259-269 nm was also performed. Method linearity from 2 to 64 $\mu\text{g mL}^{-1}$ (for both methods) aptly quantified the drug from the in-house dosage form. Chemometrics-oriented designed experiments revealed the effect of method variables such as sampling interval and scanning speed on method performance and help to define control strategies. The assay results were within the acceptable range, reproducible (%RSD < 1 %), and rugged. Overall, these two UV spectrophotometric methods served the purpose of simple and rapid quality control of NRB present in tablet dosage forms.