Optimized Spectrophotometric Methods for the Determination of Raloxifene Hydrochloride

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Abstract

To develop and optimize two spectrophotometric methods for the determination of raloxifene hydrochloride in pure and dosage forms; using Tetracyanoquinodimethane (TCNQ) and Folin Ciocalteu’s reagents. Study Design: Charge transfer reaction and chromogen formation. Place of Study: Pharmaceutical Chemistry Department, Faculty of Pharmacy, Cairo University, Egypt.

Methodology: The first method was based on the reaction of raloxifene base as a electron donor with TCNQ as π acceptor to form a green colored charge transfer complex, measured at 642.5 nm against its corresponding reagent blank in the concentration range of (2-16 Âµg/ml). The second method was based on the reaction of raloxifene hydrochloride as reducing agent with Folin Ciocalteu's reagent to form a blue colored chromogen, measured at 750 nm against its corresponding reagent blank in the concentration range of (4-32 Âµg/ml). Results: Different parameters affecting the reactions were studied including; amount of the reagent, reaction time and stability of the color. For the first method: the amount of the reagent (TCNQ) used was 1:7 molar ratio of drug: reagent, maximum color intensity was attained upon allowing the reaction to proceed in a boiling water bath for 10 minutes, the formed color was found to be stable for more than one hour, and the stoichiometry of the reaction was found to be (1:1) raloxifene hydrochloride: TCNQ. For the second method: raloxifene hydrochloride was dissolved in 10% aqueous methanolic solution, maximum color intensity was attained upon allowing the reaction to proceed for 10 minutes at room temperature and the formed color was found to be stable for about one hour. Conclusion: The methods were successfully applied for the determination of the drug in its pharmaceutical dosage form and validity of the method was assessed by applying the standard addition technique. The results were statistically compared with those obtained by the reference method showing no significant difference between them.

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