



Research article

Development and validation of colorimetric method for the determination of aminocaproic acid in bulk and pharmaceutical formulation

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Abstract

Objectives: The aim of this work was to develop a simple, accurate and feasible colorimetric method for the analysis of aminocaproic acid (ACA) in bulk and pharmaceutical formulations.

Method: The method was based on the coupling of ACA with sodium nitroprusside (SNP) to give a colored product having maximum absorption at 540 nm. The conditions affecting the reaction (SNP concentration, pH, color-developing time, temperature, and diluent solvent) were investigated.

Results: Under the optimum conditions, good linear relationship ($r = 0.9986$) was obtained between 0.2-1.0 mg/ml. The limits of detection and quantification were 0.07 mg/mL and 0.26mg/mL, respectively. The percentage recovery for the commercial preparation (Aminocaproic acid injection, 250 mg/ ml) was $100.60 \pm 2.05 \%$, ($n=3$) which reflected no interference by the injection excipients. Based on the molar ratio, the reaction stoichiometry was found to be 2:1. **Conclusion:** The developed method was validated according to ICH guidelines and proved to be accurate and precise.