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Full Papers

Validation of an Optimized Spectrophotometric Method for the Selective Determination of Labetalol Hydrochloride

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摘要 A simple sensitive and economical method for the determination of labetalol hydrochloride has been proposed, based on the reaction of labetalol with sodium nitroprusside and hydroxylamine hydrochloride in sodium dihydrogen phosphate-sodium hydroxide buffer solution of pH 12. The green-blue color produced due to the formation of a nitroso derivative has been measured at 695 nm. The Beer's range was obeyed in the concentration range of 2—51 μg•mL^{-1} with molar absorptivity of 0.48×10^4 L•mol^{-1}•cm^{-1}. Rigorous statistical analyses were performed for the validation of the method. A detailed investigation of the selectivity of the method has been done to find it to be highly selective for the determination of labetalol hydrochloride in the presence of its acidic degradation product and common excipients of formulations. The proposed method was successfully applied to the determination of labetalol hydrochloride in the laboratory prepared dosage forms. Comparison of the means of the proposed procedure with a reference method using point as well as interval hypotheses showed no statistically significant difference. The developed method was extended to investigate its applicability to biological samples.

关键词 labetalol hydrochloride sodium nitroprusside hydroxylamine hydrochloride biological sample

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