alidated Stability Indicating Spectrophotometric Methods for the Determination of Lidocaine Hydrochloride, Calcium Dobesilate, and Dexamethasone Acetate in their Dosage Forms

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Abstract

Simple, specific, accurate and precise spectrophotometric methods were developed for determination of lidocaine hydrochloride, and calcium dobesilate in their binary mixture, or combined with dexamethasone acetate as a ternary mixture; in the presence of hydroquinone, the degradation product of calcium dobesilate without prior separation. In binary mixture lidocaine hydrochloride was determined using novel mathematical methods namely amplitude subtraction and amplitude factor, in addition to ratio subtraction coupled with first derivative. While dexamathasone acetate was assayed by first derivative method. Lidocaine and dexamethasone in ternary mixture could be determined by a novel resolution technique namely successive spectrophotometric resolution; including successive ratio subtraction coupled with either first derivative, or extended ratio subtraction for dexamethasone and ratio subtraction coupled with first derivative for lidocaine hydrochloride; and finally the calcium dobesilate could be determined by first derivative, derivative ratio and the novel modified amplitude subtraction methods. The calibration curves are linear over the concentration range of 2-20 µg mL-1 for both lidocaine hydrochloride and dexamethasone acetate, 2-19 µg mL-1 or 6-50 µg mL-1 for calcium dobesilate. The proposed methods could be successfully applied to commercial pharmaceutical preparations of the cited drugs. The proposed methods were validated according to the ICH guidelines. The obtained results were statistically compared with those of the reference reported methods using student t-test, F-test, and one way ANOVA, showing no significant difference with respect to accuracy and precision.

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