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Comparative study on release of two drugs in fixed dose combination using zeroorder and first derivative spectrophotometry

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Abstract : Fixed dose combination (FDC) is a formulation of two or more active ingredients combined in a single dosage form. Development and validation of an analytical UV using derivative has been increasingly used. This method offer sensitive, simple and robust method for analyzing active ingredient in pharmaceutical dosage forms, especially when it contains more than one drug. Drug assays can also be calculated by using mathematical equation from zero derivative or absorbance spectrophotometry. This current study aimed to compare release of drugs from fixed dose combination dosage forms (pellets and microparticles) calculated by first derivative with that by zero order spectrophotometry method. As drug models, propranolol HCl and carbamazepine were used as sample of highly and poorly soluble drugs mixed in a single dosage form. Propranolol HCl and carbamazepine were mixed and loaded into sugar cores, and the drug beads were coated with 10% w/w coating level of ethylcellulose containing 20-40% w/w HPC. As microparticles, propranolol HCl was used first primary emulsion while the second primary oil phase was carbamazepine. Other type of microparticles used the opposite system. Drug release either of propranolol HCl or carbamazepine measured by zero order spectrophotometry were smoother compared to those measured by first derivative method. The validation parameter including linearity, and accuracy, have been validated statistically and recovery studies confirmed the accuracy of the proposed method. In conclusion, drug release calculated by mathematical equation from zero order spctrophomotetry offered simple, cheap and robust butaccurate, sensitive, and precise method for the determination of drugs in fixed dose combination.

Keywords : Zero order, first derivative, spectrophotometry, drug release, fixed dose combination.

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