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In vitro Drug Release Prediction of Hydrochlorothiazide Modified Release Tablet using Wagner Nelson Method and Deconvolution Approach:

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Abstract : Background: Immediate release formulation of Hydrochlorothiazide is available in market. Cmax achieved at 2 h, duration of action persist for 6-12 h, resulting in multiple dosing to maintain plasma concentration and *in vivo* activity. **Objective:** The objective of research work was to design modified release tablets of Hydrochlorothiazide 25 mg with the intention of once a day dosing. Cmax will achieve after 10 to 12 h of administration. This controlled release will constantly induce diuretic activity for whole night and day especially during early morning hours, resulting in decreased blood volume, reduced cardiac output and controlled blood pressure. When patient awakes up in morning, blood pressure will be comparatively low thus reducing the frequency of cardiac arrest. **Method:** Here an attempt has been made to kinetically calculate required in-vitro dissolution profile by deconvolution method using Wagner-nelson equation. Plasma concentration time profile of immediate release tablet 12.5 mg is available in literature and that of modified release formulation 25 mg is calculated such that Area under curve of modified release tablet matches with that of two immediate release tablets of 12.5 mg along with Cmax and Kel, thus meeting the criteria for bio-equivalency. Tmax will be delayed from 2 h to approximately 10 h. Results: In-vivo dissolution profile is calculated from the equation of "fraction of drug absorbed". Perfect IVIVC is matched when value of slope is 1, intercept is 0 and correlation coefficient (\mathbb{R}^2) 0.99. Conclusion: This in-vitro profile will be used further to develop modified release formulation.

Keywords : Area under curve, Cmax, Elimination rate constant, Deconvolution, Wagner – Nelson equation, IVIVC.

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