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Formulation Development and Stabilization of Quinapril in Low dose Pill

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Abstract : Hypertension is the most common risk factor for cardiovascular diseases, stroke and renal failure. A recent guideline by the Joint National Commission (JNC8 guidelines) recommended both angiotensin-converting enzyme (ACE) inhibitors & calcium channel blockers (CCB) as first-line drugs, in addition to diuretics. The increasing prevalence of hypertension leads to boom in the medicinal sector for the effective medications, fixed dose & multiple dose combinations are studied & provided to patient's leads to the several adverse effects to patients therefore Low Dose Single Pill Therapy got recognition. Quinapril is efficacious drug of BCS Class I (high soluble, high permeable), but it prone to degradation reactions like hydrolysis, oxidation & cyclization easily to diketopiperazine impurity. Formation of diketopiperazine is a major stability issue to the potent ACE inhibitors. Therefore a stable formulation designing is a basic challenge in the formulation of the quinapril tablets. Degradation can be observed in the tablets at processing, storage & packing stage on elevated temperature or moisture to the active moiety & formulation. Therefore formulating & is quite challenging. Formulation designed contains a magnesium carbonate as stabilizer in different process optimization which prevent API to form impurity. The optimized formulation results found are satisfactory with accelerated stability study.

Keywords: Quinapril, Low dose pill, Formulation, stabilization.

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