

FORMULATION AND DEVELOPMENT OF VALSARTAN CO-CRYSTAL

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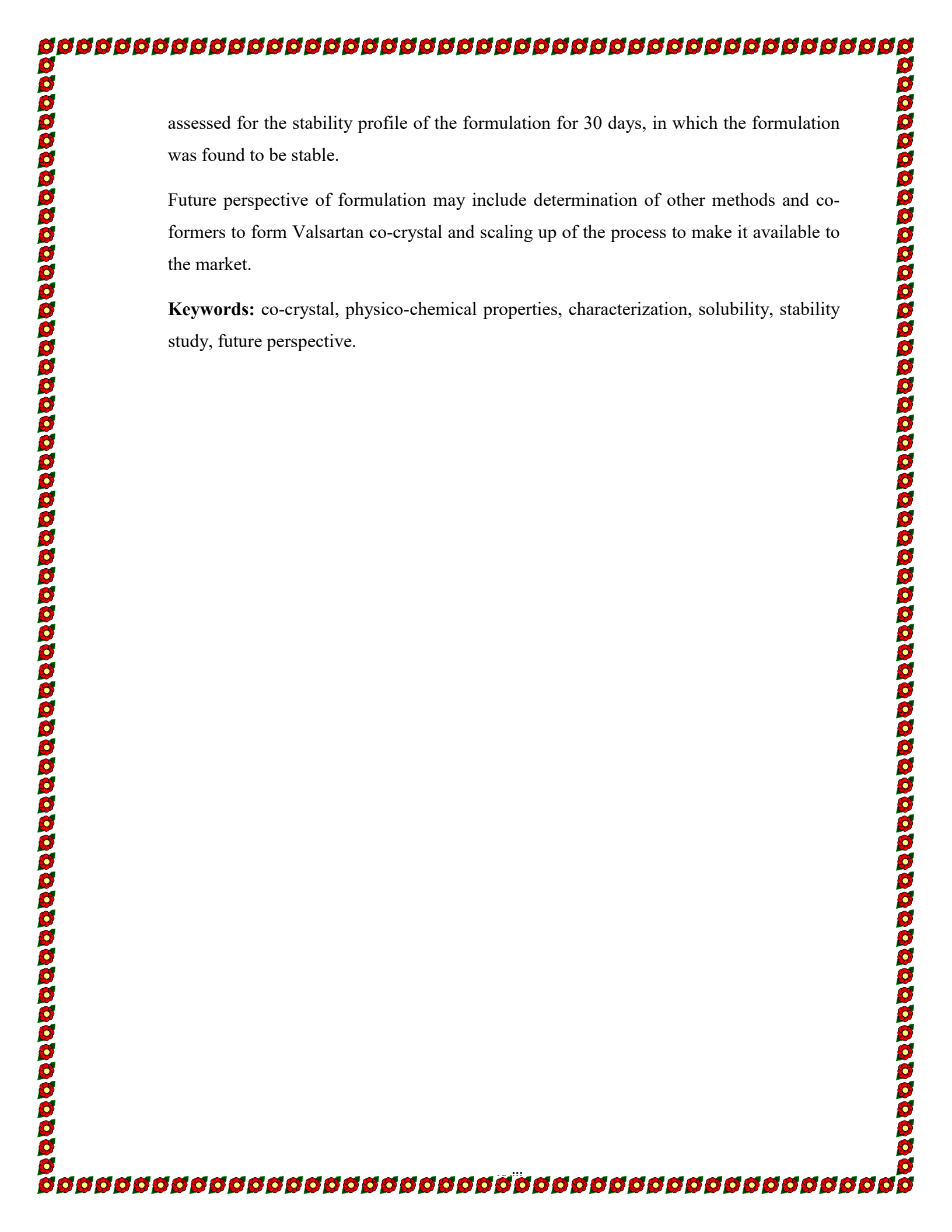
Abstract

Co-crystal is a multi-component system formed by the hydrogen bonding and π - π stacking between two components (one component is API/Drug molecule while the other component is co-former falling under GRAS category).

Co-crystals have been reported for their ability to alter/ modify pharmacokinetic and physiochemical properties of drug molecule. Though more work have been reported in regard to solubility and dissolution rate enhancement but several studies have revealed their role in improving bioavailability, permeability, hydration, photo-stability, hygroscopic stability and biochemical stability, physical form etc.

In the present research work, Valsartan co-crystals were prepared, characterized and evaluated by microscopy, fourier transform infra-red (FT-IR), differential scanning calorimetry (DSC), powder x-ray diffraction (PXRD), scanning electron microscopy (SEM), ultra-violet spectroscopy (UV) High performance liquid chromatography (HPLC). Valsartan belongs to BCS class 2 which suggest its low solubility and also that the rate determining step for the extent of bioavailability is solubility.

Positive results of enhanced saturation solubility along with enhanced in-vitro diffusion and augmentation in bioavailability was observed by the co-crystal of valsartan formed with nicotinamide as coformer by the solvent evaporation method in Methanol-Acetonitrile solvent system. Parameters such as assay and in-vitro dissolution were



assessed for the stability profile of the formulation for 30 days, in which the formulation was found to be stable.

Future perspective of formulation may include determination of other methods and co-formers to form Valsartan co-crystal and scaling up of the process to make it available to the market.

Keywords: co-crystal, physico-chemical properties, characterization, solubility, stability study, future perspective.