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(54) Title: STABILIZED INDIVIDUALLY COATED RAMIPRIL PARTICLES, COMPOSITIONS AND METHODS

(57) Abstract: The present invention relates to novel ramipril crystalline particles with improved stability and bioavailability. More particularly, the present invention is directed to individually coated, single ramipril crystalline particles for pharmaceutical and biopharmaceutical applications in oral therapies that are stabilized against decomposition into degradation products, namely, ramipril-DKP and ramipril-diacid, during formulation and storage conditions. The present invention also relates to stabilized ramipril pharmaceutical compositions, novel anhydrous pharmaceutical grade ramipril powders, methods for improving ramipril bioavailability, and methods of manufacture and stabilization of ramipril formulations. The novel, anhydrous pharmaceutical grade ramipril powders and ramipril compositions and dosage forms formed therewith are useful in the treatment of cardiovascular disorders and have the advantage that they provide greater stability against decomposition into ramipril-DKPs and ramipril-diacids under formulation and storage conditions. In addition, they maintain consistent label ramipril potency over extended shelf-life and provide reduced in vivo variability in the bioavailability of ramipril among subjects when administered orally.

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