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(54) Title: FIXED DOSE COMBINATION IN FORM OF A BILAYERED OR MONOLAYERED TABLET OF ALISKIREN AND AMLODIPINE

(57) Abstract: The present invention relates to a pharmaceutical oral fixed dose combination comprising a) a therapeutically effective amount of Aliskiren, or a pharmaceutically acceptable salt thereof, b) a therapeutically effective amount of Amlodipine, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical oral fixed dose combination shows an in vitro dissolution of component (a) of 60% or less after 10 minutes and 98% or less after 20 minutes, and a dissolution profile of component (b) of 50 % or more after 20 minutes, and 70% or more after 30 minutes at pH 2, said pharmaceutical oral fixed dose combination being bioequivalent, or close to reaching bioequivalence, to a free dose combination of Aliskiren and Amlodipine.

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