

Title (en)

PHARMACEUTICAL COMPOSITION COMPRISING RAMIPRIL AND INDAPAMIDE

Title (de)

PHARMAZEUTISCHE ZUSAMMENSETZUNG MIT RAMIPRIL UND INDAPAMID

Title (fr)

COMPOSITION PHARMACEUTIQUE COMPRENANT DU RAMIPRIL ET DE L'INDAPAMIDE

Publication

EP 3886817 A1 20211006 (EN)

Application

EP 19806009 A 20191126

Priority

- EP 18460069 A 20181127
- EP 2019082610 W 20191126

Abstract (en)

[origin: WO2020109319A1] It relates to an oral multilayer tablet comprising (a) a first layer comprising an indapamide compound, and one or more pharmaceutically acceptable excipients, and (b) a second layer comprising a ramipril compound, and a stabilizing agent; and wherein the second layer has an impurity level of (2S,3aS,6aS)-1-[(S)-2-[(S)-1- carboxy-3-phenylpropyl]amino]propanoyl]octahydrocyclopenta-[b]pyrrole2-carboxylic acid (impurity E) equal to or lower than 1.0% after 6 months at 40° C/75% RH as measured by ultra performance liquid chromatography (UPLC). It also relates to a process for the preparation of the multilayer tablet.

IPC 8 full level

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CPC (source: EP)

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Citation (search report)

See references of WO 2020109319A1

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