

Title (en)

STORAGE-STABLE ORAL DOSAGE FORM OF AMOXICILLIN AND CLAVULANIC ACID

Title (de)

LAGERSTABILE ORALE DARREICHUNGSFORM VON AMOXICILLIN UND CLAVULANSÄURE

Title (fr)

FORME D'ADMINISTRATION PAR VOIE ORALE STABLE AU STOCKAGE D'AMOXICILLINE ET D'ACIDE CLAVULANIQUE

Publication

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Application

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Abstract (en)

[origin: WO2007093425A2] The present invention relates to an airtight-packaged system comprising 1. a combination of two independently prepared pharmaceutical drug forms consisting of a drug form in aqueous formulation comprising amoxicillin trihydrate as active pharmaceutical ingredient and of a drug form prepared separately therefrom and comprising potassium clavulanate as active pharmaceutical ingredient, where the active ingredients in the combination of the two drug forms are present in a nominal ratio by weight of amoxicillin to clavulanic acid of from 20:1 to 1:1, and 1. a preparation comprising at least one desiccant in amounts such that when the packaged system is stored under stress conditions at 40°C/75% relative humidity for up to 3 months the dimerization of amoxicillin trihydrate does not exceed 1.5% by weight, and the degradation of clavulanic acid does not exceed 10% by weight.

IPC 8 full level

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