

Title (en)
MODIFIED RELEASE AMOXICILLIN PRODUCTS

Title (de)
AMOXICILLIN-PRODUKTE MIT MODIFIZIERTER FREISETZUNG

Title (fr)
PRODUITS D'AMOXICILLINE À LIBÉRATION MODIFIÉE

Publication
EP 1969134 A1 20080917 (EN)

Application
EP 06847542 A 20061208

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- US 79810906 P 20060505
- US 63331506 A 20061204
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Abstract (en)
[origin: WO2008069806A1] Disclosed are amoxicillin products comprising at least one modified release component(s), wherein the at least one modified release component(s) comprises at least amoxicillin and a pharmaceutically acceptable carrier. In some embodiments, when administered to a patient or subject in the fed state the amoxicillin products exhibit a pharmacokinetic profile for amoxicillin in the plasma characterized as follows: (1) the ratio of the portion of the AUC as measured from 2 hours post-administration to 5 hours post-administration to the portion of the AUC as measured from administration to 2 hours post-administration is at least 2.0: 1 : and (2) the ratio of the portion of the AUC as measured from 5 hours post-administration to 12 hours post-administration to the portion of the AUC as measured from administration to 2 hours post-administration is at least 1.1:1. In additional embodiments the amoxicillin products exhibit a mean in-vitro dissolution profile within a defined range characterized as follows: 1) the percent dissolved at 0.25 hours is between 25 and 55 percent; 2) the percent dissolved at 0.5 hours is between 30 and 60 percent; 3) the percent dissolved at 1 hour is between 50 and 85 percent; 4) the percent dissolved at 1.5 hours is between 70 and 95 percent; and 5) the percent dissolved at 2 hours is at least 85 percent. In preferred embodiments the amoxicillin products exhibit both of these characteristics.

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