

Title (en)

PROCESS FOR PREPARING PHARMACEUTICAL BULK MATERIAL HAVING UNIFORM DISSOLUTION

Title (de)

PROZESS ZUR MASSENHERSTELLUNG VON PHARMAZEUTISCHEM MATERIAL MIT EINHEITLICHER LÖSLICHKEIT

Title (fr)

ELABORATION D'UN PRODUIT PHARMACEUTIQUE EN VRAC UNIFORMEMENT DISSOUT

Publication

EP 1180022 A4 20040107 (EN)

Application

EP 99927538 A 19990615

Priority

- US 9913481 W 19990615
- US 13421599 P 19990514

Abstract (en)

[origin: WO0069417A1] The present invention provides a process for producing cefaclor crystalline bulk material having a dissolution rate in a capsule of $\geq 80\%$ in water in 30 minutes. One process route includes reducing the water content of cefaclor dihydrates or bulk material containing cefaclor dihydrate to produce a cefaclor form having a water content $\leq 2\%$. The cefaclor having the lower water content can then be rehydrated to a water content from 3.0 to 6.5% without adversely affecting the dissolution rate. An alternative process includes the addition of at least 0.05% of cefaclor related substances to inhibit conversion of the monohydrate to the dihydrate form.

IPC 1-7

A61K 9/48; **A61K 9/16**; **A61K 31/546**

IPC 8 full level

A61K 9/16 (2006.01); **A61K 31/545** (2006.01)

CPC (source: EP)

A61K 9/1688 (2013.01); **A61K 31/545** (2013.01)

Citation (search report)

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- See references of WO 0069417A1

Designated contracting state (EPC)

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

DOCDB simple family (publication)

WO 0069417 A1 20001123; AU 4441899 A 20001205; EP 1180022 A1 20020220; EP 1180022 A4 20040107

DOCDB simple family (application)

US 9913481 W 19990615; AU 4441899 A 19990615; EP 99927538 A 19990615