

Title (en)  
ORAL FORMULATIONS COMPRISING SITAGLIPTIN HCl MONOHYDRATE WITH IMPROVED PHARMACEUTICAL CHARACTERISTICS

Title (de)  
ORALE FORMULIERUNGEN MIT SITAGLIPTIN-HCl-MONOHYDRAT MIT VERBESSERTEN PHARMAZEUTISCHEN EIGENSCHAFTEN

Title (fr)  
FORMULATIONS ORALES COMPRENANT DU MONOHYDRATE DE HCl DE SITAGLIPTINE PRÉSENTANT DES CARACTÉRISTIQUES PHARMACEUTIQUES AMÉLIORÉES

Publication  
**EP 4045048 A4 20230524 (EN)**

Application  
**EP 19949416 A 20191014**

Priority  
TR 2019050865 W 20191014

Abstract (en)  
[origin: WO2021076066A1] An oral pharmaceutical formulation in the form of an immediate release tablet comprising sitagliptin hydrochloride, preferably monohydrate manufactured by using wet granulation method wherein croscarmellose sodium and dibasic calcium phosphate are used both in intragranular and extragranular phases. The total amount ratio of croscarmellose sodium used in intragranular and extragranular phases to the total amount of composition is between 1:5 and 5:1, preferably between 1:2 and 2:1, more preferably 1:2.5 and, the amount of ratio of dibasic calcium phosphate in intragranular to the amount of ratio of dibasic calcium phosphate in extragranular phases is 1:5, preferably 1:2, more preferably 1:1.

IPC 8 full level  
**A61K 9/20** (2006.01); **A61K 31/155** (2006.01); **A61K 31/4985** (2006.01)

CPC (source: EP)  
**A61K 9/2009** (2013.01); **A61K 9/2054** (2013.01); **A61K 31/155** (2013.01); **A61K 31/4985** (2013.01)

C-Set (source: EP)  
1. **A61K 31/4985** + **A61K 2300/00**  
2. **A61K 31/155** + **A61K 2300/00**

Citation (search report)  

- [XII] EP 2691083 B1 20170802 - KRKA TOVARNA ZDRAVIL D D NOVO MESTO [SI]
- [XII] WO 2015114152 A1 20150806 - GALENICUM HEALTH SL [ES]
- [XII] "Antidiabetic drug formulations ED - Darl Kuhn", IP.COM, IP.COM INC., WEST HENRIETTA, NY, US, 5 July 2018 (2018-07-05), XP013179268, ISSN: 1533-0001
- See also references of WO 2021076066A1

Designated contracting state (EPC)  
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

DOCDB simple family (publication)  
**WO 2021076066 A1 20210422**; EP 4045048 A1 20220824; EP 4045048 A4 20230524

DOCDB simple family (application)  
**TR 2019050865 W 20191014**; EP 19949416 A 20191014