

US010925871B2

(12) United States Patent Khera et al.

(10) Patent No.: US 10,925,871 B2

(45) **Date of Patent:** Feb. 23, 2021

(54) PHARMACEUTICAL COMPOSITIONS OF SITAGLIPTIN

(71) Applicant: CADILA HEALTHCARE LIMITED, Gujarat (IN)

(72) Inventors: **Brij Khera**, Pennington, NJ (US); **Muthaiyyan Essakimuthu Kannan**, Ahmedabad-Gujarat (IN); **Jitendra**

Rameshchandra Patel,

Ahmedabad-Gujarat (IN); Saurin

Mukundbhai Amin, Ahmedabad-Gujarat (IN)

(73) Assignee: CADILA HEALTHCARE LIMITED,

Ahmedabad (IN)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

(21) Appl. No.: 15/121,514

(22) PCT Filed: Feb. 25, 2015

(86) PCT No.: PCT/IN2015/000104

§ 371 (c)(1),

(2) Date: Aug. 25, 2016

(87) PCT Pub. No.: **WO2015/128877**

PCT Pub. Date: Sep. 3, 2015

(65) Prior Publication Data

US 2016/0367552 A1 Dec. 22, 2016

(30) Foreign Application Priority Data

Feb. 25, 2014 (IN) 651/MUM/2014

(51) Int. Cl.

A61K 31/4985 (2006.01)

A61K 9/20 (2006.01)

A61K 47/12 (2006.01)

(52) U.S. Cl.

A61K 9/16

(2006.01)

(2013.01); A61K 9/2095 (2013.01); A61K 47/12 (2013.01); A61K 9/1676 (2013.01)

(58) Field of Classification Search

None

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

6,699,871 7,326,708	B2		Edmondson et al. Cypes et al.
2009/0220609	A1*	9/2009	Mooney A61K 9/14
			424/489
2009/0247532			
2009/0264436	A1*	10/2009	McKelvey A61K 9/1635
			514/249

FOREIGN PATENT DOCUMENTS

WO	2005/020920 A2	3/2005
WO	2005/030127 A2	4/2005
WO	2005/072530 A1	8/2005
WO	2006/033848 A1	3/2006
WO	2007/035198 A2	3/2007
WO	2008/000418 A2	1/2008
WO	2009/084024 A2	7/2009
WO	2009/085990 A2	7/2009
WO	2009/120746 A2	10/2009
WO	2010/000469 A2	1/2010
WO	2010/012781 A2	2/2010
WO	2010/032264 A2	3/2010
WO	2012/131005 A1	10/2012

OTHER PUBLICATIONS

Shaon Fitzpatrick, et al.; "The development of a stable, coated pellet formulation of a water-sensitive drug, a case study: Development of a stable core formulation": Pharmaceutical Development and Technology: New York, NY, US.: vol. 11. No. 4. Jan. 1, 2006 (Jan. 1, 2006): pp. 521-528. XP008154256: ISSN: 1083-7450. DOI: 10.1080/10837450600941079: p. 522, right-hand column—p. 523: left-hand column tables p. 526, right-hand column—p. 527: left-hand column.

* cited by examiner

Primary Examiner — Bethany P Barham
Assistant Examiner — Barbara S Frazier
(74) Attorney, Agent, or Firm — Ladas & Parry LLP

(57) ABSTRACT

The present invention relates to stable oral pharmaceutical compositions of sitagliptin base and processes for the preparation thereof.

7 Claims, No Drawings