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## (54) STABLE FIXED DOSE PHARMACEUTICAL COMPOSITION COMPRISING MOMETASONE AND OLOPATADINE

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#### (56) References Cited

#### U.S. PATENT DOCUMENTS

4,871,865	A	10/1989	Lever, Jr. et al.
4,923,892	A	5/1990	Lever, Jr. et al.
5,837,699	Α	11/1998	Sequeira et al.
6,127,353	A	10/2000	Yuen et al.
7,977,376	B2	7/2011	Singh et al.
8,399,508	B2	3/2013	Singh et al.
9,078,923	B2*	7/2015	Dhuppad A61K 9/0043
2004/0097474	$\mathbf{A}1$	5/2004	Cagle et al.
2006/0110328	$\mathbf{A}1$	5/2006	Cagle et al.
2008/0058296	A1	3/2008	Chaudry
2012/0121653	$\mathbf{A}1$	5/2012	Jenkins et al.
2015/0099725	$\mathbf{A}1$	4/2015	Khairatkar-Joshi et al.
2015/0272966	Al	10/2015	Khairatkar-Joshi et al.

#### FOREIGN PATENT DOCUMENTS

WO	WO-9520393	8/1995
WO	WO-0126658	4/2001
WO	WO-2006057769 A2	6/2006
WO	WO-2009003199	12/2008
WO	WO-2010025236 A1	3/2010
WO	WO-2011008923 A2	1/2011
WO	WO-2011141929 A2	11/2011
WO	WO-2012094283	7/2012
WO	WO-2014092346 A1	6/2014

#### OTHER PUBLICATIONS

Austin, et al., Mometasone Furoate is a Less Specific Glucocorticoid than Fluticasone Propionate, Eur Respir J, 2002, 20:1386-1392.

Avicel® RC-591, Product Specification Bulletin, Feb. 2009.

Baja, et al., Benefits of Skin Prick Tests for Allergic Rhinitis, The Internet Journal of Otorhinolargyngology, 2006, 6:1.

International Search Report for International Application PCT/IB2014/064251 dated Nov. 19, 2014, pp. 1-13.

Johnson, M., Ph.D., Development of Fluticasone Propionate and Comparison with Other Inhaled Corticosteroids, J Allergy Clin Immunl, Apr. 1998, 101:4:P2:S434-S439.

Nsouli, et al., Combination of a Nasal Antihistamine Olopatadine and a Nasal Corticosteroid, Mometasone . . . , International Scientific Conference, Dubai, UAE, Dec. 2010.

Roland, et al., Olopatadine Nasal Spray for the Treatment of Seasonal Allergic Rhinitis in Patients Aged 6 years and older, Expert Opin Pharmacother, 2010, 11:9:1559-1567.

(Continued)

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#### (57) ABSTRACT

The present invention relates to a stable fixed dose aqueous pharmaceutical composition (e.g., contained in a container) for nasal administration to a human, comprising mometasone or its salt, olopatadine or its salt. The composition may further include a hydrocolloid. The invention also relates to a process for preparing the pharmaceutical composition, and the use of the pharmaceutical composition in the treatment of rhinitis in a subject.

#### 21 Claims, No Drawings