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(54) **SELF-NANOEMULSION OF POORLY SOLUBLE DRUGS**

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| ***A61K 31/216*** | (2006.01) |
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See application file for complete search history.

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO 2010150144 A2 12/2010

OTHER PUBLICATIONS

C . J . H. Porter et al., "Lipids and lipid-based formulations: opti mizing the oral delivery of lipophilic drugs," Nature Reviews Drug Discovery, vol. 6, pp. 231-248, 2007.
C. M. Hansen in Hansen Solubility Parameters : A User's Handbook, 2nd Ed., CRC Press , Boca Raton, Florida , 2007.
C. W. Pouton et al., "Formulation of lipid-based delivery systems for oral administration: Materials , methods and strategies,"Advanced Drug Delivery Reviews, vol. 60, pp. 625- 637, 2008.
Charman SA et al: "Self-emulsifying drug delivery systems: Formulation and biopharmaceutic evaluation of an Investigational lipophilic compound", Pharmaceutical Research 1992 US, vol. 9, No . 1, 1992, pp. 87-93, KP002730377.
D. W. Van Krevelen and P. J . Hoftyzer, "Properties of Polymers", 2nd Ed., Elsevier , New York, 1976, Chapter 7, pp. 129-159.
International Search Report for Application No. PCT/US2014/043198 dated Nov. 21, 2014.
J . Hildebrand and R. L. Scott, "Solubility of Nonelectrolytes", 3rd Ed., Reinhold, New York, 1950, Chapter 23, pp. 424-439.
Ming Sun et al: "Design, preparation and in vitro evaluation of paclitaxel-loaded self-nanoemulsifying drug delivery system", Asian Journal of Pharmaceutical Sciences, Jan. 1, 2011, pp. 18-25, XP055143182, Retrieved from the Internet: <http://www.asianjps.com:8080/fileup/PDF/AJPS2011,6(1)-3.pdf> [retrieved on Sep. 29, 2014].
Partial International Search Report for Application No. PCT/US2014/043198 dated Oct. 10, 2014.

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(57) **ABSTRACT**

The present disclosure pertains to pharmaceutical formulation comprising low aqueous solubility drug, a solubilizer, and optionally at least one pharmaceutically acceptable excipient that form dispersions when exposed to an aqueous environment.

**11 Claims, No Drawings**