A pharmaceutical formulation includes (1) a first dosage component comprising: a core comprising a non-ionic polymer matrix, a first amount of ondansetron or an equivalent amount of an ondansetron salt thereof dispersed within the matrix, and an electrolyte dispersed within the matrix; a first seal coat surrounding the core, the first seal coat comprising a non-ionic polymer matrix; and an immediate release drug layer surrounding the first seal coat, wherein the immediate release drug layer comprises a non-ionic polymer and a second amount of ondansetron or an equivalent amount of an ondansetron salt thereof dispersed therein; and (2) a second dosage component comprising: a core comprising a third amount of ondansetron or an equivalent amount of an ondansetron salt thereof, at least one filler, and a lubricant; and a coating surrounding the core, the coating comprising water and a mixture of methacrylic acid-alkyl acrylate copolymers with alkaline groups.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 31/4178; A61K 9/20; A61K 9/52 (2014.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61K 31/4178; A61K 9/20; A61K 9/52 (2014.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Patents and NPL (classification, keyword; search terms below)

USPC - 514/397; 424/465; 424/468; 424/472; 424/475

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)


search terms: Ondansetron Zofran Zudan Zophren sustained extended delayed controlled timely prolonged modified release fast immediate rapid release solid dosage tablet pill capsule seal coating layer filler lubricant Eudragit compressed core

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.

Y US 2008/0200508 A1 (Rarly et al.) 21 August 2008 (21.08.2008) para [0024], [0029]-[0030], [0035], [0063], [0070], [0081], [0083], [0085], [0088], [0089], [0096], [0098], [0104], [0110]-[0111], [0113]-[0114], [0117], [0132], [0135], [0140], [0142], [0152], [0159]; Fig. 4. 1-21


Y US 2008/0299197 A1 (Toneguzzo et al.) 4 December 2008 (04.12.2008) para [0042], [0108]-[0111], [0118], [0124], [0131], [0134], [0152], [0154], [0156], [0159], [0163], [0167], [0171], [0223], [0225], [0228], [0229]; Fig 2-3. 1-13, 17-20

Y US 2010/0196472 A1 (Hirsch et al.) 5 August 2010 (05.08.2010) para [0024]-[0025], [0040]-[0043], [0045], [0050], [0055], [0059]-[0061], [0063]. 1-13, 17-20

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"V" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 26 November 2014 (26.11.2014)

Date of mailing of the international search report 17 DEC 2014

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-232-3201

Authorized officer: Lee W. Young
PCT Helpdesk: 571-272-4000
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)