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(54) **Title:** FORMULATIONS OF FLIBANSERIN AND METHOD FOR MANUFACTURING THE SAME

(57) **Abstract:** The present invention provides pharmaceutical release systems comprising an therapeutically effective amount of flibanserin and at least one pharmaceutically acceptable excipient, characterized in that said pharmaceutical release systems exhibit a pharmacokinetic profile that is characterized by an average maximum flibanserin plasma concentration C_{max} lower than 300 ng/mL, preferably lower than 200 ng/mL after administration of a single dose to healthy volunteers in fasted state or directly after a meal.



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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/20 A61K9/48 A61K31/496

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)

A61K

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

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

EPO-Internal , WPI Data, BIOSIS, EMBASE, **FSTA**

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/074032 A (BOEHRINGER INGELHEIM PHARMA [DE]; BRAUNS ULRICH [DE]; BRICKL ROLF [DE]) 12 September 2003 (2003-09-12) page 1, lines 3,4,27-29 page 3, line 26 - page 4, line 21 page 5, line 5 - page 6, line 31 page 24, line 14 - page 29, line 16 page 35, lines 1-30 tables 3,4,11 figure 3	1-13
A	-----	14-23
X	WO 2006/024471 A (BOEHRINGER INGELHEIM INT [DE]; BOEHRINGER INGELHEIM PHARMA [DE]; DOLST) 9 March 2006 (2006-03-09) page 1, lines 3-16 page 2, line 27 - page 3, line 27 examples B,G-L -----	1-9, 11-13,23



Further documents are listed in the continuation of Box C.



See patent family annex.

* 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 document but published on or after the international filing date

'L' 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

"T" 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

10 July 2008

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2007/058301

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the Invitation.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM POT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1,2 partially; 3-13 fully; 23 partially

pharmaceutical release system comprising flibanserin,
pH-dependent polymer(s), pH-independent polymer(s),
pharmaceutically acceptable acid(s)

2. claims: 1,2 partially; 14-22 fully; 23 partially

pharmaceutical release system comprising a core with pH
modifier(s), first layer with water-insoluble polymer(s),
second layer with flibanserin, third layer with polymer(s)
having anionic or no ionic groups

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2007/058301

Patent document cited in search report	-	Publication date	Patent family member(s)		Publication date
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