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(54) Title: AMORPHOUS AND CRYSTALLINE FORMS OF RIVASTIGMINE HYDROGEN TARTRATE

(57) Abstract: Rivastigmine hydrogentartrate in amorphous form or in a crystalline form characterized by an X-ray powder diffraction pattern exhibiting peaks at  $2\Theta$  values of 5.1, 14.7, 16.5, 17.6, 18.6, 20.4,  $21.1^\circ \pm 0.2^\circ$  (Form I), or  $2\Theta$  values of 9.5, 11.3, 13.2, 14.1, 15.5,  $19.1 \pm 0.2^\circ$  (Form II), methods for its preparation and pharmaceutical compositions comprising the same.



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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2008/050067

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. C07C271/44    A61K31/27    A61P25/28		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) C07C   A61K   A61P		
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, BEILSTEIN Data		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/037771 A (ZENTIVA A S [CZ]; STEPANKOVA HANA [CZ]; HAJICEK JOSEF [CZ]; SIMEK STAN) 6 May 2004 (2004-05-06) cited in the application claims 1-4; example 1 -----	1,29-34
X	GB 2 203 040 A (SANDOZ LTD SANDOZ LTD [CH]) 12 October 1988 (1988-10-12) cited in the application claims 7-14 -----	29-34
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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  <p style="text-align: center;">22 April 2008</p>	Date of mailing of the international search report  <p style="text-align: center;">21/07/2008</p>	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  <p style="text-align: center;">Kleidernigg, Oliver</p>	

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2008/050067

## 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.:

see annex

### 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 PCT/ISA/ 210**

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

1. claims: 1(part), 29-34(part)

Amorphous form of rivastigmine hydrogentartrate  
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2. claims:

1(part),2,3,6(part),7(part),8(part),  
9-14,21-26(part),27,28,29-34(pa  
rt)

Polymorphic form I or rivastigmine hydrogentartrate  
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3. claims:

1(part),4,5,6(part),7(part),8(part),  
15-20,21-26(part),29-34part)

Polymorphic form II of rivastigmine hydrogentartrate  
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/EP2008/050067
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Patent document cited in search report	A	Publication date	Patent family member(s)	Publication date
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