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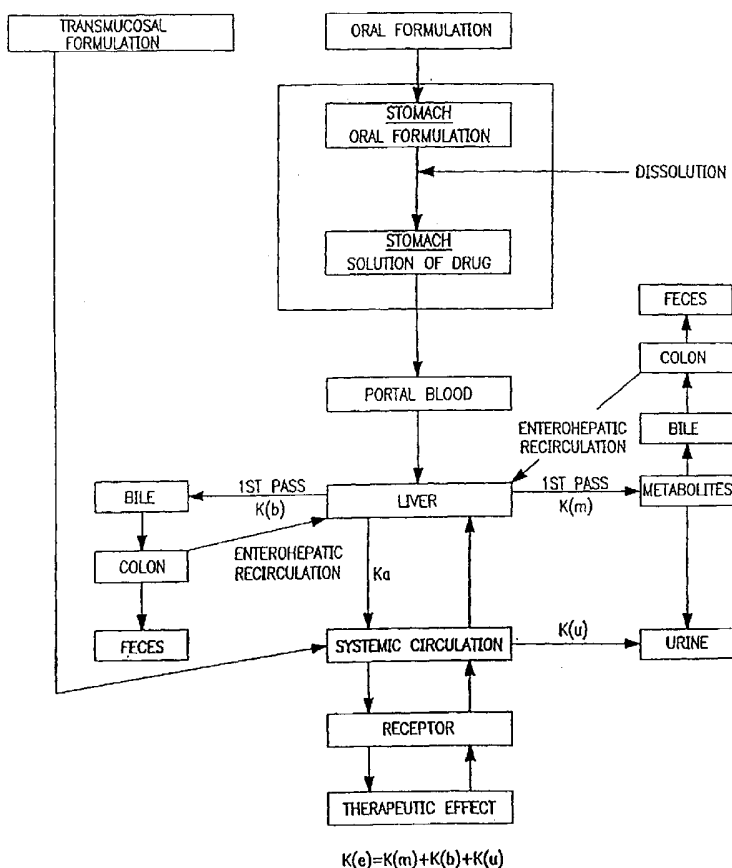
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[Continued on next page]

(54) Title: BUCCAL, POLAR AND NON-POLAR SPRAY CONTAINING ALPRAZOLAM



(57) Abstract: Buccal aerosol sprays or capsules using polar and non-polar solvents have now been developed which provide alprazolam for rapid absorption through the oral mucosa, resulting in fast onset of effect. The buccal polar compositions of the invention comprise formulation (I): aqueous polar solvent, alprazolam, and optional flavoring agent; formulation (II): aqueous polar solvent, alprazolam, optionally flavoring agent, and propellant; formulation (III): non-polar solvent, alprazolam, and optional flavoring agent; formulation (IV): non-polar solvent, alprazolam, optional flavoring agent, and propellant; formulation (V): a mixture of a polar solvent and a non-polar solvent, alprazolam, and optional flavoring agent; formulation (VI): a mixture of a polar solvent and a non-polar solvent, alprazolam, optional flavoring agent, and propellant.

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FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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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) 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, CHEM ABS Data, WPI Data, PAJ, BIOSIS, EMBASE				
<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	DATABASE CA 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; WANG, WENJU ET AL: "Alprazolam nasal spray" XP002361529 retrieved from STN Database accession no. 2002:95628 abstract & CN 1 303 674 CN (INST. OF MEDICAL INDUSTRY, SHANDONG PROV., PEOP. REP. CHINA) 18 July 2001 (2001-07-18)	1-4, 6-10,40, 57,63, 69,75, 81,87		
X	US 4 863 720 A (BURGHART ET AL) 5 September 1989 (1989-09-05) column 1, line 15 column 2, line 9 - line 34 examples 1-6	1-92		
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.				
<input checked="" type="checkbox"/> Patent family members are listed in annex.				
° Special categories of cited documents :				
<table border="0"> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> <li>*A* document defining the general state of the art which is not considered to be of particular relevance</li> <li>*E* earlier document but published on or after the international filing date</li> <li>*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)</li> <li>*O* document referring to an oral disclosure, use, exhibition or other means</li> <li>*P* document published prior to the international filing date but later than the priority date claimed</li> </ul> </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> <li>*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</li> <li>*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</li> <li>*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.</li> <li>*Z* document member of the same patent family</li> </ul> </td> </tr> </table>			<ul style="list-style-type: none"> <li>*A* document defining the general state of the art which is not considered to be of particular relevance</li> <li>*E* earlier document but published on or after the international filing date</li> <li>*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)</li> <li>*O* document referring to an oral disclosure, use, exhibition or other means</li> <li>*P* document published prior to the international filing date but later than the priority date claimed</li> </ul>	<ul style="list-style-type: none"> <li>*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</li> <li>*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</li> <li>*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.</li> <li>*Z* document member of the same patent family</li> </ul>
<ul style="list-style-type: none"> <li>*A* document defining the general state of the art which is not considered to be of particular relevance</li> <li>*E* earlier document but published on or after the international filing date</li> <li>*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)</li> <li>*O* document referring to an oral disclosure, use, exhibition or other means</li> <li>*P* document published prior to the international filing date but later than the priority date claimed</li> </ul>	<ul style="list-style-type: none"> <li>*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</li> <li>*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</li> <li>*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.</li> <li>*Z* document member of the same patent family</li> </ul>			
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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  VON EGGELKRAUT, S			

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 International Application No  
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/33621 A (F.H. FAULDING & CO. LIMITED; SWAMINATHAN, KIVALUR, SUBRAMANIASARMA; HA) 18 September 1997 (1997-09-18)  example 5 page 3, line 7 - line 19 -----	1-10, 22-24, 27,28, 40-48, 57,59, 61,63, 65,67, 69,71, 73,75, 77,79, 81,83, 84,87, 89,92
X	WO 01/72338 A (FARMARC NEDERLAND BV; PENKLER, LAWRENCE, JOHN) 4 October 2001 (2001-10-04)  page 6, paragraph 4 - paragraph 5 page 10, last paragraph page 12, paragraph 3 example 8 -----	1-4, 8-10,57, 63,69, 75,81,87
X	WO 95/31217 A (A/S DUMEX ; SONNE, MATTE, RYDAHL) 23 November 1995 (1995-11-23)  example 17 -----	1-4, 8-10, 22-24, 27,28, 41-44, 46-48, 57,59, 61,63, 65,67, 69,71, 73,75, 77,79, 81,83, 85,87, 89,91
X	US 4 863 970 A (PATEL ET AL) 5 September 1989 (1989-09-05) column 17; examples VII-CC -----	22,25,26
A	US 2003/077227 A1 (DUGGER HARRY A) 24 April 2003 (2003-04-24) the whole document -----	

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/031797

## Box 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:  
  
Although claims 9,10, 20, 21, 27, 28, 38, 39, 47, 48, 55-92 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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 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:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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.

No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No

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