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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STABLE PHARMACEUTICAL DOSAGE FORM COMPRISING HMG-CoA REDUCTASE INHIBITOR

(57) Abstract: The present invention relates to stable pharmaceutical dosage forms comprising the active substances sensitive to environmental influences and pharmaceutical excipients which provide stability of one or more active substance to pH of the environment and do not contain alkalizing or buffering substances or combinations thereof. Said invention also discloses the stable pharmaceutical dosage forms comprising the active substances sensitive to pH of the environment, oxidation and/or environmental humidity, pharmaceutical excipients which provide stability of the active substance to pH of the environment and the coating which provides protection of the active substance from environment influences, in particular from oxidation and/or environmental humidity. Further the invention discloses the procedures for the preparation of the stable pharmaceutical dosage form and use of such active substances for the preparation of the pharmaceutical dosage forms for the treatment of dyslipidemias, cardiovascular disease and other diseases.



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INTERNATIONAL SEARCH REPORT

International Application No
PCT/SI2004/000008

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/22 A61K9/20 A61K9/28

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 7 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, PAJ, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 465 096 A (MERCK & CO INC) 8 January 1992 (1992-01-08) abstract examples 12-16	1-5, 7-16, 18-29
X	EP 0 375 156 A (MERCK & CO INC) 27 June 1990 (1990-06-27) abstract examples 3-7	1-5, 7-14, 18-29
X	WO 98/15264 A (LOEFROTH JAN ERIK ; ASTRA AB (SE); OEDMAN JONAS (SE)) 16 April 1998 (1998-04-16) abstract examples 5.1-5.5	1-5, 15, 16, 18-29
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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
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- *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
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Date of the actual completion of the international search

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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 01/76566 A (DOROSSIEV IVO ; FOX MICHAEL (IL); TEVA PHARMA (IL); TEVA PHARMA (US)) 18 October 2001 (2001-10-18) abstract examples 5,8 -----	1-6, 25-29
X	US 5 916 595 A (CHOU JOSEPH ET AL) 29 June 1999 (1999-06-29) abstract claims 1-12; examples 1-3 -----	1-5,25, 29
X	WO 01/37876 A (BAYER AG ; BAGI CEDO M (US)) 31 May 2001 (2001-05-31) abstract claims 1-10; examples 3-6 -----	1-6, 25-29
P,X	WO 03/057195 A (ATHPHARMA LTD ; BUTLER JACKIE (IE); DEVANE JOHN (IE); STARK PAUL (IE)) 17 July 2003 (2003-07-17) abstract examples 1,2,4-6 -----	1-5, 25-29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SI2004/000008

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.: 30
because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 30 is 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

Information on patent family members

International Application No

PCT/SI2004/000008

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