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(54) Title: REPAGLINIDE SUBSTANTIALLY FREE OF DIMER IMPURITY

(57) Abstract: The present invention provides highly pure repaglinide substantially free of dimer impurity, and process for the preparation thereof. The present invention also relates to 2-ethoxy-N-[(1S)-3-methyl-1-[2-(1-piperidinyl)phenyl]butyl]-4-[2-[(1S)-3-methyl-1-[2-(1-piperidinyl)phenyl]butyl]amino]-2-oxoethyl]benzamide, an impurity of repaglinide, and a process for preparing and isolating thereof. The present invention further relates to pharmaceutical compositions comprising solid particles of pure repaglinide substantially free of dimer impurity or pharmaceutically acceptable salts thereof, wherein 90 volume-percent of the particles (D₉₀) have a size of less than about 400 microns. The present invention also provides an optical resolution method of racemic 3-methyl-1-(2-piperidino-phenyl)-1-butylamine and use thereof for the preparation of repaglinide.

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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)

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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)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	GRELL W ET AL: "REPAGLINIDE AND RELATED HYPOGLYCEMIC BENZOIC ACID DERIVATIVES" JOURNAL OF MEDICINAL CHEMISTRY, US AMERICAN CHEMICAL SOCIETY, WASHINGTON, vol. 41, 1 January 1998 (1998-01-01), pages 5219-5246, XP000872800 ISSN: 0022-2623 the whole document	1-4, 48-69
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See patent family annex.

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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.
A	KRISHNA REDDY, K.V.S.R. ET AL.: "Impurity profile study of repaglinide" JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS, vol. 32, 2003, pages 461-467, XP002509504 figure 1	1-96
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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