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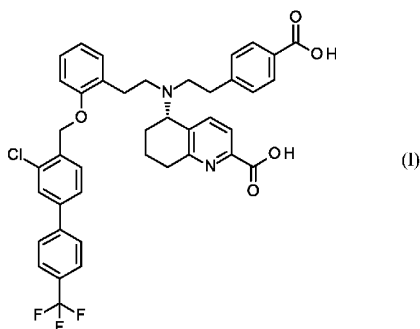
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(54) Title: PROCESS FOR PREPARING (5S)-{[2-(4-CARBOXYPHENYL)ETHYL] [2-(2-{[3-CHLORO-4'-(TRIFLUOROMETHYL)BIPHENYL-4-YL]METHOXY}PHENYL)ETHYL]AMINOL-5,6,7,8-TETRAHYDROQUINOLINE-2-CARBOXYLIC ACID AND ITS CRYSTALLINE FORMS FOR USE AS PHARMACEUTICALLY ACTIVE COMPOUND



(57) Abstract: The present invention relates to a novel and improved process for preparing (5S)-{[2-(4-carboxyphenyl)ethyl][2-(2-{[3-chloro-4'-(trifluoromethyl)biphenyl-4-yl]methoxy}phenyl)ethyl]aminol-5,6,7,8-tetrahydroquinoline-2-carboxylic acid of the formula (I) and to novel crystalline forms of it, which is i.a. the pseudopolymorphic form monohydrate I (I-M-I) or the pseudopolymorphic form monohydrate II (I-M-II), furthermore the present invention relates to a novel and selective crystallization process for preparation of the pseudopolymorphic form monohydrate I (I-M-I) or the pseudopolymorphic form monohydrate II (I-M-II), preferably monohydrate I of formula (I-M-I) and to pharmaceutical compositions comprising monohydrate I of formula (I-M-I) and to its use for the treatment and/or prevention of diseases, in particular for the treatment and/or prevention of pulmonary and cardiopulmonary and cardiovascular diseases.

[Continued on next page]

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