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(54) **Title:** CRYSTALS OF LAQUINIMOD SODIUM AND IMPROVED PROCESS FOR THE MANUFACTURE THEREOF

(57) **Abstract:** The present application provides subject-matter related to a mixture of crystalline laquinimod sodium particles, wherein (i) > 90% of the total amount by volume of the laquinimod sodium particles have a size of < 40 µm or (ii) > 50% of the total amount by volume of the laquinimod sodium particles have a size of < 15 µm and wherein one or more of further requirements are fulfilled with regard to bulk density, tapped density and the amount of certain impurities. The present application also provides a pharmaceutical composition comprising an amount of laquinimod and at least one of BH-3-HLAQ, MCQ, MCQCA, MCQME, NEA, and MCQEE. The subject invention also provides processes for preparing BH-3-HLAQ, MCQ, MCQCA, MCQME, MCQEE, and compounds prepared by said processes. Further provided is a process for testing whether a sample of laquinimod contains an undesirable impurity. Further provided are processes for (a) preparing a validated pharmaceutical composition comprising laquinimod, (b) distributing a validated batch of a pharmaceutical composition comprising laquinimod, (c) validating a batch of a pharmaceutical product containing laquinimod and (d) preparing a packaged pharmaceutical composition comprising laquinimod, each comprising determining the amount of at least one of BH-3-HLAQ, MCQ, MCQCA, MCQME, NEA, and MCQEE in a sample or batch. The subject invention further provides use of BH-3-HLAQ, MCQ, MCQCA, MCQME, MCQEE as a reference standard to detect trace amounts of the impurity in a pharmaceutical composition comprising laquinimod. Finally, the subject invention provides methods of determining the concentration of BH-3-HLAQ, MCQ, MCQCA, MCQME, MCQEE, 5-HLAQ, SPIRO-LAQ or 3 H-LAQ in a pharmaceutical composition comprising laquinimod.

