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(54) Title: PHARMACEUTICAL COMPOSITIONS COMPRISING RIFAXIMIN AND AMINO ACIDS, PREPARATION METHOD AND USE THEREOF

(57) Abstract: The object of the present invention concerns rifaximin compositions comprising amino acids, characterized in that they increase rifaximin solubility in aqueous solutions. Rifaximin compositions comprising amino acids are useful in the treatment of disease wherein amino acids and rifaximin are efficacious. The present invention relates to pharmaceutical compositions comprising rifaximin or one of the pharmaceutically acceptable salts thereof and one or more amino acid(s), wherein the molar ratio between the amino acid(s) and rifaximin is comprised between 1:1 and 10:1, preferably between 1:1 and 5:1, together with pharmaceutically acceptable excipients. Moreover, the present invention relates to rifaximin crystals characterized in that they are obtained by means of a process comprising: a) dissolution of the compositions of rifaximin and amino acids, wherein amino acids and rifaximin are in a molar ratio comprised between 1:1 and 10:1 according to Claim 1, in solutions formed by ethanol/water, in a volumetric ratio comprised between 1:1 and 1:10 (v/v); b) evaporation of the solution obtained in step a) at temperatures comprised between room temperature and 40°C, in a time period comprised between 1 and 10 days; wherein the resulting crystals have monoclinic space group  $P2_1$  and cell parameters comprised in the ranges: a: 13.7(1)-13.8(1) Å; b: 19.7(1)-19.9 (1) Å; c: 16.4(6)-16.6(6) Å;  $\beta$ : 92.1 (1)-91.9(1) deg.



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