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(54) Title: MICROEMULSION & SUB-MICRON EMULSION PROCESS & COMPOSITIONS

(57) Abstract: There is provided a process for the preparation of an oil in water (O/W) microemulsion or sub-micron emulsion composition for dermal delivery of at least one pharmaceutically active ingredient, the method including the steps of a) Admixing a first part including at least one of the group consisting of animal, mineral or vegetable oils, silanes, siloxanes, esters, fatty acids, fats, halogen compounds or alkoxyated alcohols; and one or more lipophilic surfactants, and a second part including water and at least one hydrophilic surfactant to achieve homogeneity, b) heating the mix of step a) to a phase assembly temperature in the range of 40 - 99°C, preferably 45 - 95°C, more preferably 65 - 85°C with continuous mixing to obtain a microemulsion or sub-micron emulsion, c) allowing said microemulsion or sub-micron emulsion to cool, and d) adding a third part to said microemulsion or sub-micron emulsion at a temperature between 2°C and said phase assembly temperature, said third part if necessary being premixed and heated until the components are dissolved and including at least one component selected from the group consisting of non-surfactant amphiphilic type compound, surfactant and water with the proviso that when the third part includes water it also includes a non-surfactant amphiphilic type compound and/or surfactant. The phase assembly temperature can be determined visually by the achievement of translucence in the composition or by measures such as conductivity which peaks and then is maintained at a plateau whilst phase assembly occurs. It has been found that whilst if a non-surfactant amphiphilic type compound such as the polyol is added together with the second part as would conventionally be the case, a microemulsion or sub-micron emulsion is not formed, by adding the so called third part, phase assembly occurs at a lower temperature than would be expected and moreover, this phase appears to assist in maintaining the microemulsion or sub-micron emulsion characteristics of the formulation during storage at normal temperatures.

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