as the sole solvent, high amounts of TPGS (50% to 99.9%) are required.

U.S. Patent 5,583,105 describes pre-concentrated emulsion containing the active ingredient cyclosporine in a lipophilic and/or amphiphilic solvent. In this composition TPGS is mentioned as an emulsifier, adjuvant and antioxidant for fat oils. The antioxidant effect on a pharmaceutical active ingredient, and especially on a NK2 receptor antagonist, is not claimed.

WO2006036614 describes materials like surfactants suitable for solid formulations. The TPGS row material of waxy consistency is converted into properly shaped solid that can be incorporated for example into tablets. The use of the solid form for the preparation of solutions and/or emulsions is not described.

EP1216025 describes the use of a wide range of TPGS as a surfactant (from 0.1% to 90%) in solid formulations comprising a dispersant soluble in water and a soluble compound in lipid medium as a lipase inhibitor. The solidified mixture is loaded into HPMC capsules that reveal an increase in the efficiency and power.

Formulations for topical use containing TPGS and layers of alpha-tocopherol to solubilize or emulsify water insoluble drugs are mentioned in WO9531217.

TPGS is described as a stabilizer applied for the formation and stabilization of double-layer liposomes in acid environment (US5, 364.631).

In WO9808490 the preparation of solid co-precipitated for oral delivery of lipophilic substances with poor biodisponibility is described. Delivery tests are conducted on dry powders.

SUMMARY OF DISCLOSURE

In the first aspect, there is provided a liquid aqueous oral pharmaceutical composition comprising nepadutant as active ingredient and an additive and optionally a chelating agent and optionally other pharmaceutical acceptable excipients, characterized in that the selected additive is TPGS.

In the first aspect, there is provided a process for the preparation of the compositions as disclosed herein, comprising a step wherein nepadutant is mixed with TPGS, and optionally with a chelating agent.

DESCRIPTION OF THE INVENTION

The present invention relates to stable oral, liquid, pharmaceutical compositions containing Nepadutant and TPGS, even for paediatric use for the treatment of newborns and infants (nurslings) in the period from birth to

one year, and preferably, from birth to six months of age.

The TPGS is a substance with solubilizer and antioxidant activity therefore acts as a stabilizer of substances which are highly unstable to oxidation. In addition, the TPSG is essentially tasteless and therefore suitable and acceptable for use in neonates and nurslings. Surprisingly the use of TPGS results in a solubilizing and antioxidant action allowing to obtain limpid, stable solutions of Nepadutant and acceptable from an organoleptic point of view. Additional excipients commonly used with TPGS, such as lipophilic or hydrophilic non-aqueous solvents or co-solvents, lipophilic antioxidant