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(54) Title: FORMULATION OF DOXYLAMINE AND PYRIDOXINE AND/OR METABOLITES OR SALTS THEREOF

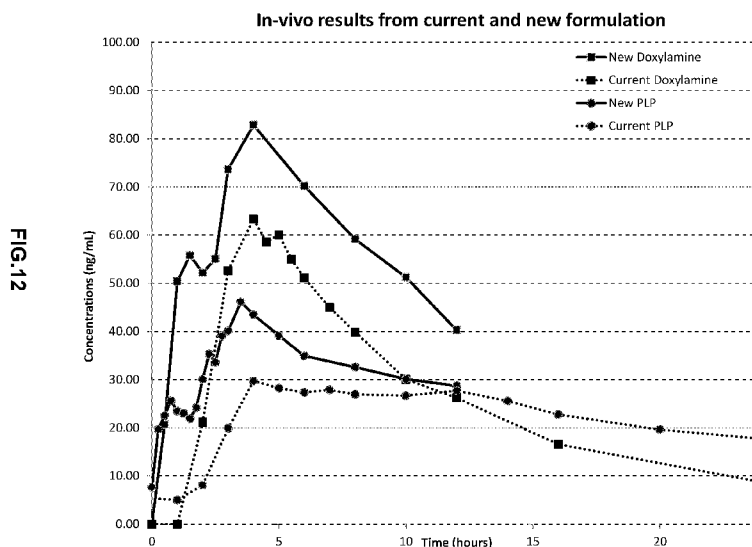


FIG. 12

(57) **Abstract:** A dual release oral dosage system/dosage form comprising an immediate release component/composition and a delayed release component/composition is described. Each of the immediate release component/composition and delayed release component/composition comprises one or more of doxylamine, an analog thereof, a derivative thereof, a prodrug thereof, a metabolite thereof and/or a salt thereof, and one or more of pyridoxine, a salt thereof, a metabolite thereof and/or a salt of the metabolite. The dual release oral dosage system/dosage form exhibits an improved pharmacokinetic profile relative to the current Diclectin® formulation and is useful for example for the alleviation of the symptoms of nausea and vomiting, for example in the case of nausea and vomiting in pregnancy (NVP).

