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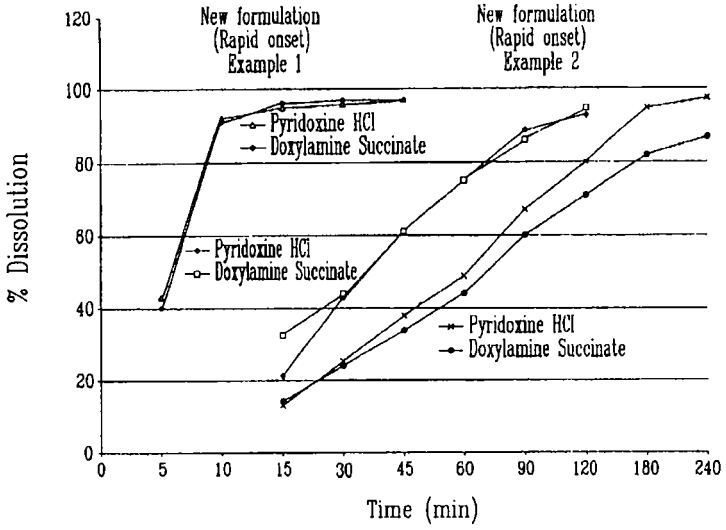
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(54) Title: RAPID ONSET FORMULATION



(57) Abstract: Provided herein is a novel enterically-coated pyridoxine HCl and doxylamine succinate rapid onset formulation comprising a disintegrating agent such that the following dissolution profiles are satisfied when measured in 1000 ml phosphate buffer at pH 6.8 and 37 °C in tape 2 dissolution apparatus at 100 rpm: (a) at least about 40 % of the total pyridoxine HCl and doxylamine succinate is dissolved after 30 minutes of measurement; (b) at least about 70 % of the total pyridoxine HCl and doxylamine succinate is dissolved after 60 minutes of measurement; (c) at least about 80 % of the total pyridoxine HCl and doxylamine succinate is dissolved after 90 minutes of measurement; (d) at about 90 % of the total pyridoxine HCl and doxylamine succinate is dissolved after 120 minutes of measurement. Preferably the formulation will contain a core coated with at least one enteric coating, the core comprising pyridoxine HCl, doxylamine succinate and the following non-active excipients: a filler or binder, a disintegrating agent, a lubricant, a silica flow conditioner and a stabilizing agent.

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ACTION

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