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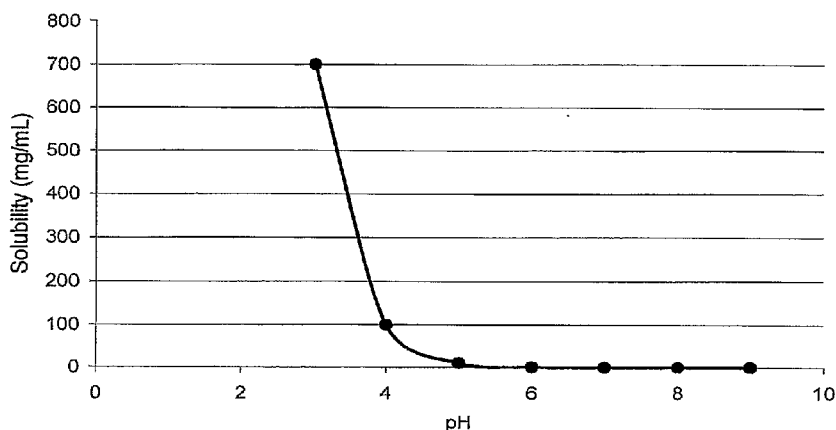
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(54) Title: DRUG DELIVERY SYSTEMS COMPRISING WEAKLY BASIC DRUGS AND ORGANIC ACIDS

pH - solubility Profile of
Ondansetron Hydrochloride Dihydrate



(57) Abstract: A pharmaceutical dosage form such as a capsule, a conventional or orally disintegrating tablet capable of delivering a nitrogen (N)-containing therapeutic agent having a pKa in the range of from about 5 to 14 into the body in a sustained- released fashion, in order to be suitable for a twice- or once-daily dosing regimen, comprises at least one organic acid, which solubilizes the therapeutic agent the drug prior to releasing it into the hostile intestinal environment wherein said weakly basic drug is practically insoluble. The unit dosage form is composed of a multitude of multicoated particulates (*i.e.*, immediate-release beads, sustained-release beads and/or one or more timed, pulsatile-release bead populations) is designed in such a way that said weakly basic drug and said organic acid do not come into close contact during processing and/or storage for in-situ formation of acid addition compounds while ensuring that the acid is not depleted prior to completion of the drug release.

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