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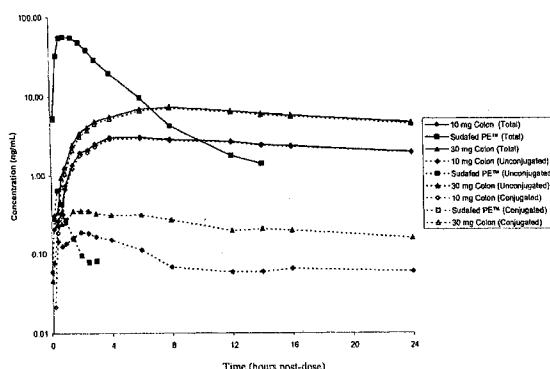
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[Continued on next page]

(54) Title: PHENYLEPHRINE PHARMACEUTICAL FORMULATIONS AND COMPOSITIONS FOR COLONIC ABSORPTION



(57) Abstract: The invention discloses a pharmaceutical composition comprising phenylephrine or a pharmaceutically acceptable salt thereof and an erodible layer which is for oral administration wherein the composition delivers phenylephrine or a pharmaceutically acceptable salt thereof via absorption in the colon. The pharmaceutical composition comprises a core comprising phenylephrine or a pharmaceutically acceptable salt thereof and an erodible layer which is in a time-dependent, pH-dependent, or colon-specific enzyme-dependent erodible layer that degrades to expose the core to release phenylephrine in the colon. In one preferred embodiment, the erodible layer encases the core. The composition optionally further comprises phenylephrine in the erodible layer or other additional layer(s). The pharmaceutical composition can further comprise one or more additional therapeutically active agents selected from one or more of the group consisting of antihistamines, analgesics, anti-pyretics, and non-steroidal anti-inflammatory agents. The invention also discloses methods of administering phenylephrine via the colon, thereby increasing the bioavailable amount of therapeutically active unconjugated phenylephrine relative to the total phenylephrine in the plasma.

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