Summary of the Invention

In one embodiment, the present invention relates to use of a pharmaceutical composition in the manufacture of a medicament for treating a gastrointestinal disorder wherein said pharmaceutical composition is to be administered to a patient regardless of whether the patent is under fasting or fed conditions independently of the intake or consumption of food or meal;

wherein said pharmaceutical composition comprises a therapeutically effective amount of a dosage form comprising:

(a) a first solid particle, wherein said first solid particle comprises dexlansoprazole and a first enteric coating, wherein the first enteric coating releases the dexlansoprazole from the solid particle at a pH of about 5.0 to about 5.5; and

(b) a second solid particle, wherein said second solid particle comprises dexlansoprazole and a second enteric coating, wherein the second enteric coating releases the dexlansoprazole from the solid particle at a pH of about 6.2 to about 6.8; and

wherein the first solid particle is present in the pharmaceutical composition in an amount of from about 15% to about 50% by weight of the pharmaceutical composition and the second solid particle is present in the pharmaceutical composition in an amount of from about 50% to about 85% by weight of the pharmaceutical composition; and

wherein the changes in pharmacokinetics after administration to the patient of a therapeutically effective amount of the pharmaceutical composition under fasting or fed conditions do not produce statistically significant changes in intragastric pH; and

wherein the gastrointestinal condition is heartburn, inflammatory bowel disease, Crohn's disease, irritable bowel syndrome, ulcerative colitis, a peptic ulcer, a stress ulcer, a bleeding peptic ulcer, a duodenal ulcer, infectious enteritis, colitis, diverticulitis, gastric hyperacidity, dyspepsia, gastroparesis, Zollinger-Ellison syndrome, gastroesophageal reflux disease, *Helicobacter pylori* associated disease, short-bowel syndrome, hypersecretory states associated with systemic mastocytosis or basophilic leukemia or hyperhistaminemia or combinations of any of the above disorders.

In one embodiment, the present invention relates to a method of treating a gastrointestinal disorder in a patient in need of treatment thereof. The method comprises the steps of:

administering to said patient a pharmaceutical composition comprising a therapeutically effective amount a proton pump inhibitor, wherein said pharmaceutical composition is capable of being administered to a patient independent of the intake of food.

In another embodiment, the present invention relates to a method of treating a gastrointestinal disorder in a patient in need of treatment thereof. The method comprises the steps of:

administering to said patient a pharmaceutical composition comprising a therapeutically effective amount of:

(a) a first solid particle, wherein said first solid particle comprises an active agent and a first enteric coating, wherein the first enteric coating releases the active agent from the solid particle at a pH of about 5.0 to about 5.5; and

(b) a second solid particle, wherein said second solid particle comprises an active agent and a second enteric coating, wherein the second enteric coating releases the active agent from the solid particle at a pH of about 6.2 to about 6.8;

wherein the first solid particle comprises from about 15% to about 50% by weight of the pharmaceutical composition and the second solid particle comprises from about 50% to about 85% by weight of the pharmaceutical composition; and

further wherein said pharmaceutical composition is capable of being administered to a patient independent of the intake of food.

In the above method, the first solid particle can be a granule. Additionally, the second solid particle can be a granule. Preferably, both the first and second solid particles are each granules. Preferably, the pharmaceutical composition is a tablet or capsule.

The active agent in the first solid particle can be dexlansoprazole. The active agent in the second solid particle can be dexlansoprazole. Preferably, the active agent in the first solid particle and the second solid particle is dexlansoprazole.

WHAT IS CLAIMED:

1. Use of a pharmaceutical composition in the manufacture of a medicament for treating a gastrointestinal disorder wherein said pharmaceutical composition is to be administered to a patient regardless of whether the patent is under fasting or fed conditions independently of the intake or consumption of food or meal;

wherein said pharmaceutical composition comprises a therapeutically effective amount of a dosage form comprising:

(a) a first solid particle, wherein said first solid particle comprises dexlansoprazole and a first enteric coating, wherein the first enteric coating releases the dexlansoprazole from the solid particle at a pH of about 5.0 to about 5.5; and

(b) a second solid particle, wherein said second solid particle comprises dexlansoprazole and a second enteric coating, wherein the second enteric coating releases the dexlansoprazole from the solid particle at a pH of about 6.2 to about 6.8; and

wherein the first solid particle is present in the pharmaceutical composition in an amount of from about 15% to about 50% by weight of the pharmaceutical composition and the second solid particle is present in the pharmaceutical composition in an amount of from about 50% to about 85% by weight of the pharmaceutical composition; and

wherein the changes in pharmacokinetics after administration to the patient of a therapeutically effective amount of the pharmaceutical composition under fasting or fed conditions do not produce statistically significant changes in intragastric pH; and

wherein the gastrointestinal condition is heartburn, inflammatory bowel disease, Crohn's disease, irritable bowel syndrome, ulcerative colitis, a peptic ulcer, a stress ulcer, a bleeding peptic ulcer, a duodenal ulcer, infectious enteritis, colitis, diverticulitis, gastric hyperacidity, dyspepsia, gastroparesis, Zollinger-Ellison syndrome, gastroesophageal reflux disease, *Helicobacter pylori* associated disease, short-bowel syndrome, hypersecretory states associated with systemic mastocytosis or basophilic leukemia or hyperhistaminemia or combinations of any of the above disorders.

2. The use of claim 1, wherein the first enteric coating releases the dexlansoprazole at a pH of about 5.5.

3. The use of claim 2, wherein the first enteric coating comprises a methacrylic acid copolymer dispersion.

4. The use of any preceding claim, wherein the second enteric coating releases the dexlansoprazole at a pH of about 6.75.