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(54) Title: PROCESS FOR PREPARING A REACTIVE PHARMACEUTICAL PRODUCT FOR THE DETECTION OF GASTROINTESTINAL DISORDER CAUSED BY BACTERIA IN THE GASTROINTESTINAL SUPERIOR TRACT

(57) Abstract

The invention relates to the diagnosis in a human or lower animal subject of a gastrointestinal disorder of the upper gastrointestinal tract caused by bacteria using a breath test. In one aspect the invention provides a process for the preparation of a reactive pharmaceutical product for the detection of gastrointestinal disorder caused by bacteria in the superior gastrointestinal tract, characterized by the preparation of a dense powdered vehicle or granules of sugar, or granules of Nu–pareil seeds, of a specific diameter between 0.12 to 3.0 mm and soluble in gastric fluids; dispersing in or coating on the vehicle a micro dose of ^{14}C–urea; and coating or encapsulating the resulting blend with an inert gelatin substance that dissolves rapidly, thereby obtaining a capsule, wherein the density of the vehicle is such that it allows deposition of the isotope contained in the capsule onto the gastrointestinal tract mucosa. In another aspect the invention provides a pharmaceutical product for breath tests for the detection of gastrointestinal disorder that comprises an isotope of ^{14}C–urea dispersed in or coated on a dense powdered or granulated vehicle of sugar, Nu–pareil seeds, and the resulting blend being coated with or enclosed in inert gelatin substance that dissolves rapidly in the presence of gastric juice, wherein the vehicle has a density sufficient to allow the capsule contents to be deposited onto the gastrointestinal tract mucosa, and wherein the granules have a diameter of between 0.12 to 3.0 mm.