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Marshall**

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

(76) Inventor: **Barry J. Marshall**, 40 Beatrice Street, Dalkeith, Western Australia 6009 (AU)

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Primary Examiner—Michael G. Hartley

(74) Attorney, Agent, or Firm—Dority & Manning P.A.

(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 ¹⁴C-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 ¹⁴C-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.

20 Claims, No Drawings