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Sparks et al.

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[54] **CONTROLLED RELEASE POWDER AND PROCESS FOR ITS PREPARATION**

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[*] Notice: The portion of the term of this patent subsequent to Aug. 28, 2007 has been disclaimed.

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Related U.S. Application Data

[63] Continuation of Ser. No. 169,447, Mar. 17, 1988, Pat. No. 4,952,402, which is a continuation of Ser. No. 792,801, Oct. 30, 1985, Pat. No. 4,940,588.

[30] Foreign Application Priority Data

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[51] Int. Cl.⁵ **A61K 9/58; A61K 9/60**

[52] U.S. Cl. **424/419; 424/486; 424/487; 424/488; 424/497; 424/501; 424/502; 514/974**

[58] Field of Search **424/419, 486, 487, 488, 424/501, 502, 497; 514/974**

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[57] **ABSTRACT**

A controlled release powder containing discrete micro-particles for use in edible, pharmaceutical and other controlled release compositions is disclosed. The micro-particles have an average size in the range of from 0.1 to 125 μm . Each of the micro-particles is in the form of a micromatrix of an active ingredient uniformly distributed in at least one non-toxic polymer. The micro-particles have a predetermined release of active ingredient when the dissolution rate thereof is measured according to the Paddle Method of U.S. Pharmacopoeia XX at 37° C. and 75 r.p.m.

12 Claims, 16 Drawing Sheets

