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(12) **United States Patent**  
**Frontanes et al.**

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- (54) **STABLE THYROID HORMONE PREPARATIONS AND METHOD OF MAKING SAME**
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- (\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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- (51) **Int. Cl.**<sup>7</sup> ..... **A61K 9/20**; A61P 5/14
- (52) **U.S. Cl.** ..... **424/488**; 424/464; 424/465; 514/960
- (58) **Field of Search** ..... 424/488, 464, 424/465; 514/960

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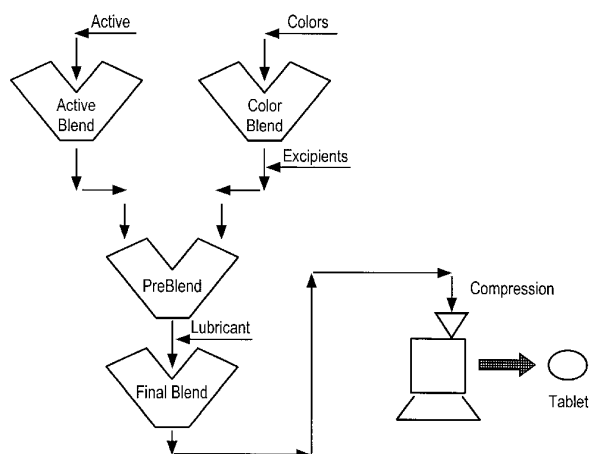
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(57) **ABSTRACT**

Provided is a pharmaceutical preparation of thyroid hormone and a process of making a tablet formulation of the pharmaceutical preparation using direct compression. In a preferred embodiment, the pharmaceutical preparation comprises levothyroxine sodium and silicified microcrystalline cellulose.

**15 Claims, 16 Drawing Sheets**



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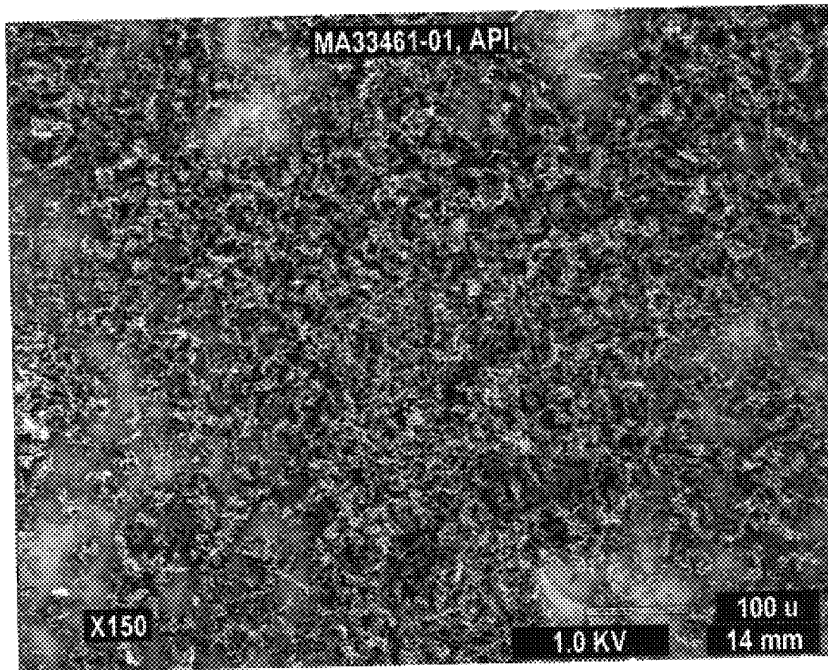


FIG. 1A

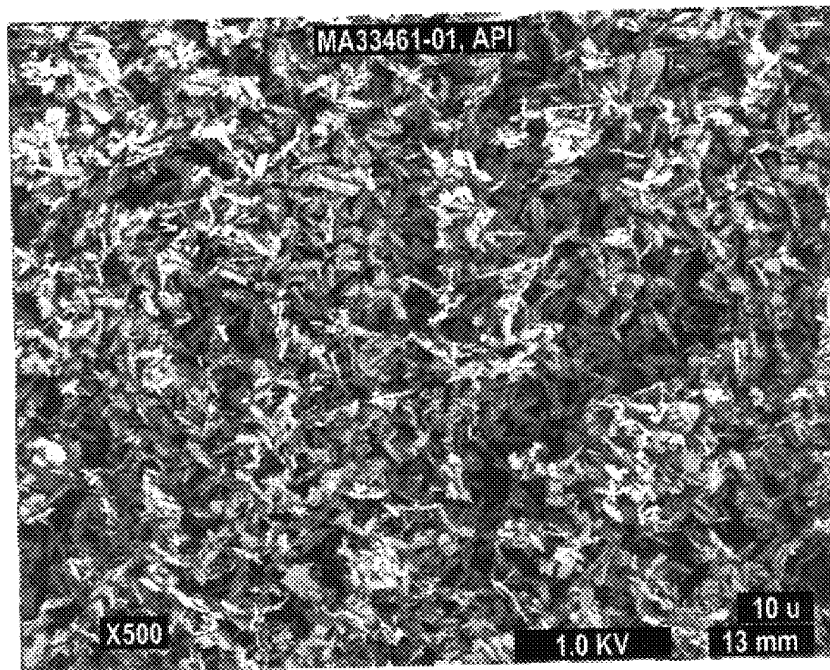


FIG. 1B



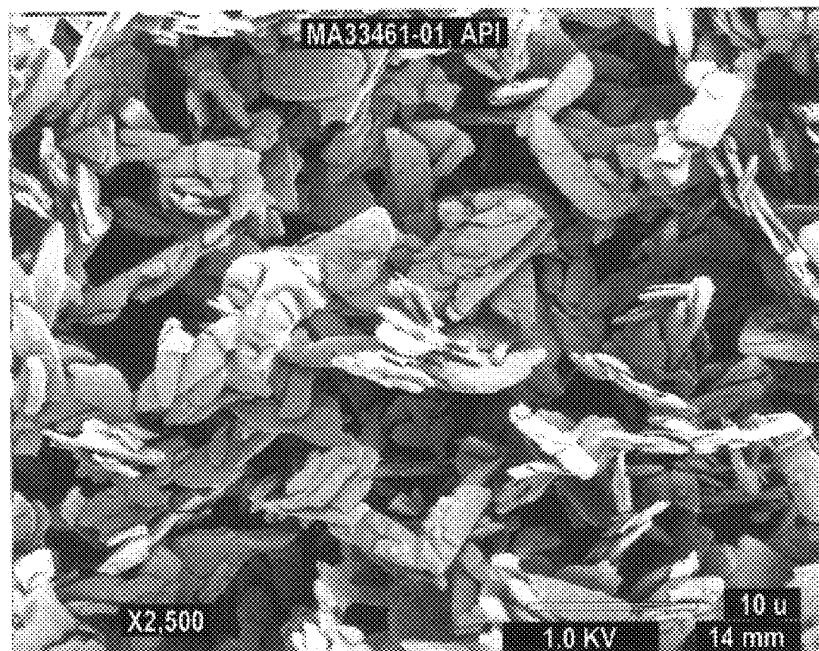


FIG. 1C

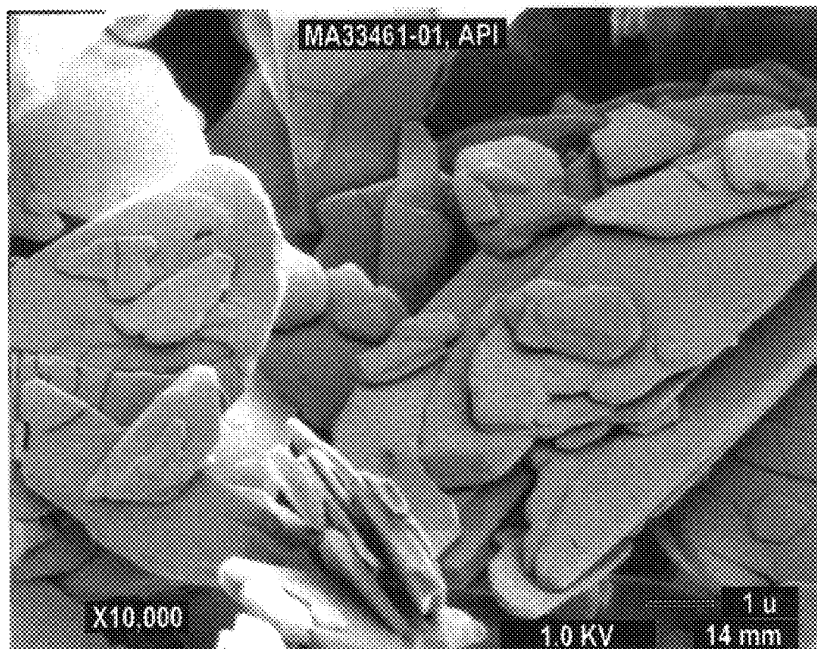


FIG. 1D



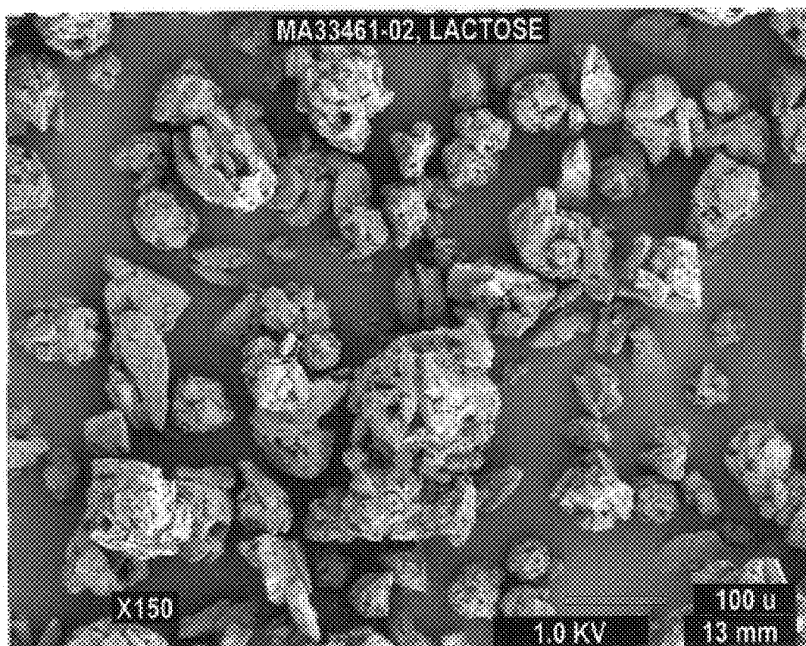


FIG. 2A

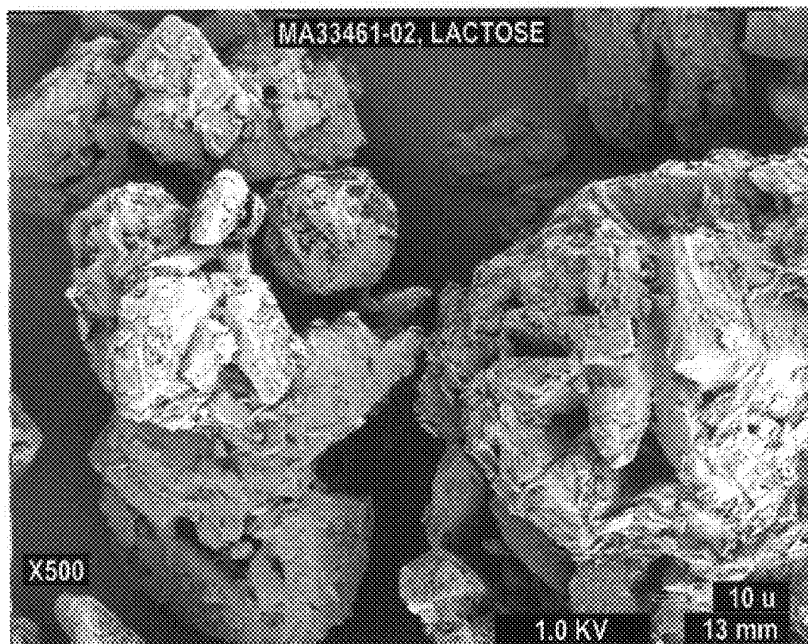


FIG. 2B

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