of the formulation, based on the total weight of the formulation excluding any additional coatings or shells (wt%), which is effective to maintain a difference of less than 30% between the amount of vitamin D compound released at any given time point after four hours during in vitro dissolution after two months exposure to storage conditions of 25°C and 60% relative humidity and the amount released at the same dissolution time point during in vitro dissolution conducted prior to exposing the formulation to the storage conditions.

[0007b] In a further aspect of the present disclosure, there is provided a sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a formulation disclosed herein.

[0007c] In another aspect of the present disclosure, there is provided a product, which is a stabilized formulation for sustained release or a sustained release dosage form disclosed herein, for use in the treatment of a vitamin-D responsive disease.

[0007d] In a further aspect of the present disclosure, there is provided a use of a product, which is a stabilized formulation for sustained release or a sustained release dosage form disclosed herein, in the manufacture of a medicament for the treatment of a vitamin-D responsive disease.

[0008] The present disclosure comprises a controlled release Vitamin D formulation comprising a vitamin D compound and a cellulosic compound.

[0009] The present disclosure also comprises a storage-stabilized formulation for controlled release of a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation. In one example, the stabilized formulation comprises one or both of 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3 and a stabilizing agent or stabilizing compound,

WHAT IS CLAIMED:

1. A stabilized formulation for sustained release of a vitamin D compound, the formulation comprising a mixture of:

one or both of 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3; and

a stabilizing agent comprising a material selected from the group consisting of: cellulose compounds, poloxamers, poly(ethylene oxide) polymers, povidones, fumed silicas, and combinations thereof, wherein the stabilizing agent is present in an amount of at least about 5% of the formulation, based on the total weight of the formulation excluding any additional coatings or shells (wt%), which is effective to maintain a difference of less than 30% between the amount of vitamin D compound released at any given time point after four hours during in vitro dissolution after two months exposure to storage conditions of 25°C and 60% relative humidity and the amount released at the same dissolution time point during in vitro dissolution conducted prior to exposing the formulation to the storage conditions.

2. The formulation of claim 1, comprising a matrix that releasably binds and controllably releases the one or both of 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3.

3. The formulation of claim 1 or 2, comprising a lipophilic matrix comprising the one or both of 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3.

4. The formulation of claim 3, wherein the lipophilic matrix comprises a wax.

5. The formulation of any one of the preceding claims, wherein the formulation is an oral formulation for sustained release of the vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation.

6. The formulation of any one of the preceding claims, wherein the stabilizing agent comprises a cellulosic compound.

7. The formulation of claim 6, wherein the cellulosic compound comprises a cellulose ether.

8. The formulation according to claim 7, wherein the cellulose ether comprises one or more of methylcellulose, hydroxyl propyl methylcellulose, hydroxyl ethyl methylcellulose, hydroxyl ethyl cellulose, and hydroxyl propyl cellulose.

9. The formulation according to claim 8, wherein the cellulosic compound comprises hydroxypropyl methylcellulose.

10. The formulation according to any one of the preceding claims, wherein the vitamin D compound comprises 25-hydroxyvitamin D3.

11. A sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a formulation according to any of the preceding claims.

12. The sustained release dosage form according to claim 11, wherein the dosage form contains 5 to 80 µg of 25-hydroxyvitamin D3, preferably 30 µg or 60 µg of 25-hydroxyvitamin D3.

13. A product, which is a stabilized formulation for sustained release according to any one of claims 1-10 or a sustained release dosage form according to any one of claims 11-12, for use in the treatment of a vitamin-D responsive disease.

14. Use of a product, which is a stabilized formulation for sustained release according to any one of claims 1-10 or a sustained release dosage form according to any one of claims 11-12, in the manufacture of a medicament for the treatment of a vitamin-D responsive disease.

15. The product for use according to claim 13 or use according to claim 14, wherein the vitamin-D responsive disease:

(a) is selected from cancer, dermatological disorders, parathyroid disorders, bone disorders and autoimmune disorders; or

(b) is selected from psoriasis, hyperparathyroidism, secondary hyperparathyroidism and osteoporosis; or

(c) is secondary hyperparathyroidism.

16. The product for use or use according to any one of claims 13 to 15, wherein the patient:

(a) has chronic kidney disease (CKD); or

(b) has chronic kidney disease which is Stage 3 or 4; or

(c) has chronic kidney disease which is Stage 3 or 4 and vitamin D insufficiency; or

(d) has chronic kidney disease which is Stage 3 or 4 and vitamin D deficiency.

17. The product for use according to claim 13 or use according to claim 14, wherein the vitamin-D responsive disease is hyperparathyroidism secondary to Chronic Kidney Disease.

18. The product for use or use according to claim 17, wherein the vitamin-D responsive disease is hyperparathyroidism secondary to Chronic Kidney Disease Stage 3 or 4.

19. The product for use or use according to any one of claims 13 to 18, wherein the patient is:

(a) human; or

(b) an adult human.

20. The product for use or use according to any one of claims 13 to 19, wherein 5 to 80 µg of 25-hydroxyvitamin D3, preferably 30 µg or 60 µg of 25-hydroxyvitamin D3, is to be administered per day.