Claims:

1. A stable tablet-in-tablet pharmaceutical composition comprising a fixed dose combination of cyclophosphamide and capecitabine, wherein the stable tablet-in-tablet pharmaceutical composition comprises (a) an inner core comprising cyclophosphamide and one or more pharmaceutically acceptable excipient, wherein the said inner core is coated with seal coat; and (b) an outer surrounding coat comprising capecitabine and one or more pharmaceutically acceptable excipients.

2. The stable tablet-in-tablet pharmaceutical composition according to claim 1, wherein the inner core comprising 20 to 60 mg of cyclophosphamide.

3. The stable tablet-in-tablet pharmaceutical composition according to claim 1, wherein the outer surrounding coat comprising 50 to 1800 mg of capecitabine.

4. The stable tablet-in-tablet pharmaceutical composition according to claim 1, wherein the inner core comprising cyclophosphamide having d90 particle size less than 100 microns.

5. The stable tablet-in-tablet pharmaceutical composition according to claim 1, wherein the one or more pharmaceutically acceptable excipientsare selected from the group consisting of one or more diluents, one or more binders, one or more disintegrantes, one or more glidants, one or more lubricants, one or more plasticizer, one or more opacifying agent, one or more colorants and combinations thereof.

6. The stable tablet- in-tablet pharmaceutical composition according to claim 1, wherein the inner core comprising cyclophosphamide is prepared by direct compression comprising following steps:

   (a) mixing the cyclophosphamide with one or more diluent, one or more binder and one or more disintegrant in suitable mixer to form a first mixture;

   (b) lubricating the first mixture obtained in step (a) by blending with a suitable sifted lubricant to form a lubricating mixture;

   (c) compressing the lubricating mixture obtained in step (b) into a tablet; and

   (d) coating the tablet to prepare the inner core portion as cyclophosphamide tablet.

7. The stable tablet-in-tablet pharmaceutical composition according to claim 1, wherein the outer surrounding coat comprising capecitabine granules is prepared by wet granulation method comprising following steps:

(a) sifting of capecitabine, one or more diluent, a portion of disintegrant through appropriate mesh and mixing in a suitable mixer to form a dry mixture;

(b) dissolving a binder in a solvent to produce a granulation liquid;

(c) granulating the dry mixture obtained in step (a) using the granulation liquid of step

(b) to form wet granules;

(d) drying the wet granules obtained in step (c) to form dried granules and optionally screening the dried granules;

(e) blending the dried granules obtained in step (d) with remaining portion of disintegrant and sifted glidant to form blended granules; and

(f) lubricating the blended granules obtained in step (e) with sifted lubricant to prepare the outer surrounding coat.

8. The stable tablet-in-tablet pharmaceutical composition according to claim 1, wherein the said composition comprising at least 90% of the cyclophosphamide and capecitabine when stored for 6 month at 2-8°C, 25°C / 60% RH and 30°C / 75% RH.