CLAIMS

1. An oral contraceptive composition comprising 2 mg of 17α-cyanomethyl-17-ß-hydroxyestra-4,9-dien-3-one (dienogest, DNG) and 0.02 mg of 17α-ethinylestradiol (ethynyl estradiol, EE), wherein the pharmaceutical form of said contraceptive composition is an extended release form, wherein EE is intended for slow or controlled release, the dissolution profile of EE in said composition being characterized in that:
   (i) no more than 25% of the amount initially present in said composition is dissolved within 1 hour; and
   (ii) between 30% and 60% of the amount initially present in said composition is dissolved within 2 hours;

   when the composition is subjected to an *in vitro* dissolution test according to USP1 (baskets) method using 900 mL of water at 37°C (± 0.5°C) at a stirring rate of 75 rpm.

2. The oral contraceptive composition of claim 1, wherein the pharmaceutical form of said contraceptive composition is an extended release form, wherein all the content of DNG and EE are intended for controlled release.

3. The oral contraceptive composition according to claim 1 or 2, wherein the extended release form is a tablet, optionally coated, which comprises one or more release rate controlling excipients and wherein dienogest (DNG) and ethynyl estradiol (EE) are dispersed within an extended release matrix including said one or more release rate controlling excipients.

4. The oral contraceptive composition according to any one of claims 1 to 3, wherein said tablet is a film-coated tablet wherein the film coating is for immediate disintegration.

5. The oral contraceptive composition according to any of claims 1 to 4, wherein said composition presents a pharmacokinetic profile further to oral administration under fasting conditions once daily for 7 days characterized by:
   a. a Tmax of DNG from 3.5h to 4h, preferably around 3.75h; and
   b. a Tmax of EE from 3.5h to 4h, preferably around 3.75h.

6. The contraceptive composition according to any of claims 1 to 5, wherein when the composition is subjected to an *in vitro* dissolution test according to USP1 (baskets) method, and DNG and EE, respectively, has a dissolution profile characterized in that:

(i) no more than 25% of the amount initially present in said composition is dissolved within 1 hour; and

(ii) between 30% and 60% of the amount initially present in said composition is dissolved within 2 hours,

(iii) at least 70%, of the amount initially present in said composition is dissolved within 8 hours.

7. The contraceptive composition according to claim 6, wherein DNG and EE, respectively, has a dissolution profile characterized in that:

(i) no more than 25% of the amount initially present in said composition is dissolved within 1 hour;

(ii) between 35% and 55% of the amount initially present in said composition is dissolved within 2 hours, and

(iii) at least 80% of the amount initially present in said composition is dissolved within 5 hours.

8. The contraceptive composition according to any of claims 1 to 7, wherein said composition is suitable for administration as the daily active oral form in a contraceptive regimen comprising the administration of the active oral form daily for 21 to 24 consecutive days followed by a period of 4 to 7 days of daily administration of a placebo oral form or no oral form administration.

9. The contraceptive composition according to claim 8, wherein said composition is suitable for administration as the daily active oral form in a contraceptive regimen comprising the administration of the active oral form for 24 consecutive days followed by a period of 4 days of daily administration of a placebo oral form.

10. The contraceptive composition according to any of claims 1 to 9, wherein said extended-release matrix comprises a hydrophilic polymer, preferably said matrix is obtained by granulation of DNG and EE with said hydrophilic polymer.

11. The contraceptive composition according to claim 10, wherein said hydrophilic polymer is a cellulosic derivative, preferably a hydroxyalkyl cellulose, at a range from 25% to 60% w/w, preferably from 30% to 50% w/w, more preferably from 45% to 55% w/w, even more preferably around 50% w/w.

12. The contraceptive composition according to any of claims 10 or 11, wherein said hydrophilic polymer is selected from hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose (HPMC) and a combination thereof, preferably said hydrophilic polymer is HMPC, more preferably HPMC K100.

13. The contraceptive composition according to any of claims 1 to 12, wherein said composition comprises:

- a diluent selected from the group consisting of corn starch, microcrystalline cellulose, powdered cellulose, silicified cellulose, lactose monohydrate, anhydrous lactose, mannitol, sorbitol, sucrose, fructose, dextrose, and/or mixtures thereof, preferably at 30-60% w/w;
- a polymeric matrix forming agent selected from the group of gums, hydroxyalkyl cellulose derivatives, hydrophilic acrylic polymers, ammonium alginate, sodium alginate, potassium alginate, calcium alginate, propylene glycol alginate, alginic acid, polyvinyl alcohol, povidone (PVP), carbomer, potassium pectate, potassium pectinate, protein derived materials, ethyl cellulose, hydrophobic acrylic polymers and polyvinylacetate (PVAc) based polymers, long chain (C8-C50, especially C12-C40), substituted or unsubstituted hydrocarbons, such as fatty acids, fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol, myristyl alcohol, fatty acids, mineral and vegetable oils and waxes such as beeswax, carnauba wax, microcrystalline wax, ozokerite, polyalkylene glycol, and/or mixtures thereof, preferably at 10-60% w/w;
- a binder selected from the group consisting of polyvinylpyrrolidone, sodium carboxymethyl cellulose, calcium carboxymethyl cellulose, and/or mixtures thereof, preferably at 1-10% w/w; and
- a lubricant selected from the group consisting of talc, alkaline earth salts of stearic acid, specially magnesium and calcium stearate, stearic acid, glycerin palmitostearate, stearyl fumarate, and/or mixtures thereof, preferably at 0-5% w/w.

14. The contraceptive composition according to any of claims 1 to 13, wherein said composition comprises:

- lactose, preferably lactose monohydrate, at 35-45 % w/w;
- HPMC, preferably HPMC K100 low viscosity, at 45-55% w/w;

- povidone, preferably povidone K30, at 2 -7 % w/w; and
- magnesium stearate at 1-3 % w/w.

15. A process for obtaining a contraceptive composition as described in any of claims 1 to 14, wherein said method comprises:

i. independently mixing each of DNG and EE with a diluent selected from the group consisting of corn starch, microcrystalline cellulose, powdered cellulose, silicified cellulose, lactose monohydrate, anhydrous lactose, mannitol, sorbitol, sucrose, fructose, dextrose, and/or mixtures thereof, and then mixing these together to obtain a mixture;

ii. granulating a diluent selected from the group consisting of corn starch, microcrystalline cellulose, powdered cellulose, silicified cellulose, lactose monohydrate, anhydrous lactose, mannitol, sorbitol, sucrose, fructose, dextrose, and/or mixtures thereof and a polymeric matrix forming agent selected from the group of gums, hydroxyalkyl cellulose derivatives, hydrophilic acrylic polymers, ammonium alginate, sodium alginate, potassium alginate, calcium alginate, propylene glycol alginate, alginic acid, polyvinyl alcohol, povidone (PVP), carbomer, potassium pectate, potassium pectinate, protein derived materials, ethyl cellulose, hydrophobic acrylic polymers and polyvinylacetate (PVAc) based polymers, long chain (C8-C50, especially C12-C40), substituted or unsubstituted hydrocarbons, such as fatty acids, fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol, myristyl alcohol, fatty acids, mineral and vegetable oils and waxes such as beeswax, carnauba wax, microcrystalline wax, ozokerite, polyalkylene glycol, and/or mixtures thereof;

iii. drying, optionally sieving, and mixing the granules obtained in step ii) with the mixture obtained in step i);

iv. blending the mixture obtained in step iii) with a lubricant selected from the group consisting of talc, alkaline earth salts of stearic acid, especially magnesium and calcium stearate, stearic acid, glycerin palmitostearate, stearyl fumarate, and/or mixtures thereof, and then compress into tablets;

v. optionally coating the tablets obtained in step iv) with a coating agent and dry.

16. A contraceptive kit comprising one or more packaging units wherein each packaging unit comprises at least 21 to 24 oral contraceptive compositions according to any of claims 1

to 8 or 10 to 14 as daily active dosage forms and at least 4 to 7 daily placebo dosage forms.

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