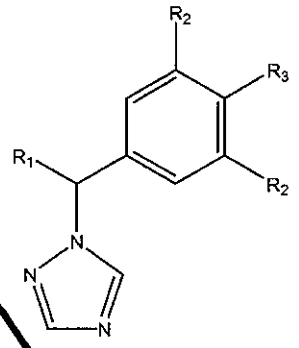
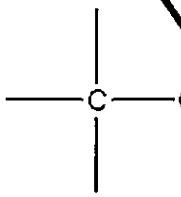
CLAIMS

1. Composition suitable for forming an *in situ* intramuscular implant comprising a biodegradable thermoplastic polymer of polylactic acid (PLA), DMSO and an aromatase inhibitor compound of general formula (1):



(1)

wherein:

When R_1 is H; R_2 is  and R_3 is H

When R_1 is  R_2 is H and R_3 is CN

characterised in that the aromatase inhibitor compound is in suspension in a solution containing DMSO and PLA and represents between 15-50% by weight of the total composition, with the composition being able to solidify, to form a solid or gel-type *in situ* implant on contact with an aqueous fluid or that of the body, with therapeutic values after *in vivo* administration of at least 100 nmol/mL for more than 60 days.

2. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the aromatase inhibitor compound is in suspension in a solution containing DMSO and PLA and represents between 20-30% by weight of the total composition.

3. Composition suitable for forming the *in situ* intramuscular implant of any of the claims 1 or 2 **wherein** the aromatase inhibitor compound is in suspension in a solution containing DMSO and PLA and represents 25% by weight of the total composition.

4. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the aromatase inhibitor compound of general formula (1) has the following particle size distribution in the formulation:

- < 10% of the particles less than 20 microns,
- < 10% of the particles greater than 350 microns and
- d0.5 between 70-200 microns.

5. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the aromatase inhibitor compound is letrozole or anastrozole, either alone or in combination.

6. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the solution containing DMSO and PLA is 40-43% by weight of PLA (100% lactic) and 57-60% by weight of DMSO.

7. Composition suitable for forming the intramuscular implant of claim 1 **wherein** the terminating group of the PLA is an ester.

8. Composition suitable for forming the *in situ* intramuscular implant of any of the previous claims **wherein** the formulation is irradiated at a maximum value of 35 kGy.

9. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the ratio between DMSO and the aromatase inhibitor compound of general formula (1) is in the range of 0.5 to 3.7.

10.- Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the ratio between DMSO and the aromatase inhibitor compound of general formula (1) is in the range of 1.7 to 1.8.

11. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the viscosity of the solution containing DMSO and PLA is in the range between 0.8 and 1.8 Pa.s.

12. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the maximum volume of the composition is 2 mL containing 500 mg of letrozole for intramuscular injection.

13. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the AUC of the burst of the compound of general formula (1) must be less than 10% of the total AUC and not more than 50% of the total AUC over the first 30 days after injection.

14. Use of the composition of claims 1 to 13 as a medicine for treating breast cancer.

15. Kit suitable for the *in situ* preparation of the composition of any of the claims 1 to 13 wherein the aromatase inhibitor compound of general formula (1) and the polymer in solid form are in a first container and the DMSO is in a second separate container.

16. Kit suitable for the *in situ* preparation of an implant of claim 15 wherein the polymer is lyophilised.

17. Kit suitable for the *in situ* preparation of the composition of any of the claims 1 to 13 wherein the aromatase inhibitor compound of general formula (1) is in a first container in solid form and the DMSO and the polymer are in a second container in solution.

18. Kit suitable for the *in situ* preparation of the composition of any of the claims 1 to 13 wherein the aromatase inhibitor compound of general formula (1), the polymer and the DMSO are in a single container in the form of a suspension.

CLAIMS

1. Composition suitable for forming an *in situ* intramuscular implant comprising a biodegradable thermoplastic polymer of polylactic acid (PLA), DMSO and an aromatase inhibitor compound that is letrozole or anastrozole, either alone or in combination, wherein the composition solidifies to form a solid or gel-type *in situ* implant on contact with an aqueous or body fluid,
characterised in that the aromatase inhibitor compound is in suspension in a solution containing DMSO and PLA and represents between 15-50% by weight of the total composition.

2. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the aromatase inhibitor compound is in suspension in a solution containing DMSO and PLA and represents between 20-30% by weight of the total composition.

3. Composition suitable for forming the *in situ* intramuscular implant of any of the claims 1 or 2 **wherein** the aromatase inhibitor compound is in suspension in a solution containing DMSO and PLA and represents 25% by weight of the total composition.

4. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the aromatase inhibitor compound has the following particle size distribution in the formulation as measured by the technique of laser ray diffraction in water suspension until obscuration of 9.41%:

- < 10% of the particles less than 20 microns,
- < 10% of the particles greater than 350 microns and
- d0.5 between 70-200 microns.

5. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the solution containing DMSO and PLA is 40-43% by weight of PLA (100% lactic) and 57-60% by weight of DMSO.

6. Composition suitable for forming the intramuscular implant of claim 1 **wherein** the terminating group of the PLA is an ester.

7. Composition suitable for forming the *in situ* intramuscular implant of any of the previous claims **wherein** the formulation is irradiated at a maximum value of 35 kGy.

8. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the weight ratio between DMSO and the aromatase inhibitor compound is in the range of 1.75 to 1.8.

9. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the viscosity of the solution containing DMSO and PLA is in the range between 0.8 and 1.8 Pa.s measured at 25 °C using a rotational viscometer.

10. Composition suitable for forming the *in situ* intramuscular implant of claim 1 **wherein** the maximum volume of the composition is 2 mL containing 500 mg of letrozole for intramuscular injection.

11. Kit for the *in situ* preparation of the composition of any of the claims 1 to 10 wherein the aromatase inhibitor compound and the polymer in solid form are in a first container and the DMSO is in a second separate container.

12. Kit of claim 11 wherein the polymer is lyophilised.

13. Kit of claim 11 wherein the aromatase inhibitor compound is in a first container in solid form and the DMSO and the polymer are in a second container in solution.

14. Kit of claim 11 wherein the aromatase inhibitor compound, the polymer and the DMSO are in a single container in the form of a suspension.