CLAIMS

1. Process for preparing and purifying a 3-carboxylic ester of allopregnanolone which comprises:
   - reacting isoallopregnanolone with a strong carboxylic acid having a pka ≤ 3 under Mitsunobu conditions;
   - precipitating the 3-carboxylic ester of allopregnanolone in a solvent system comprising water and an organic solvent; and
   - recrystallizing the precipitate of the 3-carboxylic ester of allopregnanolone in a non-polar solvent.

2. Process for preparing allopregnanolone which comprises:
   - obtaining a 3-carboxylic ester of allopregnanolone by the process as defined in claim 1; and
   - subjecting the 3-carboxylic ester of allopregnanolone thus obtained to hydrolysis under neutral conditions, mild basic conditions or energetic basic conditions.

3. Process according to any one of claims 1-2, wherein the carboxylic acid is selected from the group consisting of mono-, di-, and trifluoroacetic acid, mono-, di-, and trichloroacetic acid, cyanoacetic acid, and orto-nitrobenzoic- and dinitrobenzoic acid.

4. Process according to any one of claims 1-3, wherein the 3-carboxylic ester of allopregnanolone is precipitated in a solvent system comprising water and a water-soluble organic solvent.

5. Process according to any one of claims 1-4, wherein the 3-carboxylic ester of allopregnanolone is precipitated in a solvent system comprising water and a water-soluble organic solvent selected from 1,4-dioxane, acetone, acetonitrile, DMF, methanol, ethanol, isopropanol or their mixtures,
   and / or
   the precipitate of the 3-carboxylic ester of allopregnanolone is recrystallized in a non-polar solvent selected from group consisting of hexane, cyclohexane, heptane, toluene, iPr_2O, MeOtBu or their mixtures.

6. Process according to any one of claims 1-5, wherein the 3-carboxylic ester of allopregnanolone is subjected to hydrolysis with an alcohol without adding any acid or base.

7. Process according to any one of claims 1-5, wherein the 3-carboxylic ester of allopregnanolone is subjected to hydrolysis with a base whose conjugate acid has a pKa ≤ 11 such as an alkali or alkaline earth carbonate or bicarbonate.

8. Process according to any one of claims 1-5, wherein the 3-carboxylic ester of allopregnanolone is subjected to hydrolysis with a base whose conjugate acid has a pKa ≥ 12, such as an alkali or alkaline earth C_{1-6} alkoxide or hydroxide, for a time and at a temperature suitable to keep the level of 3α-hydroxy-5α,17α-pregnan-20-one in an amount of 0.5% or less.

9. Process according to claim 8, wherein the hydrolysis is carried out for not more than about 2 h and/or at a temperature of about 15-40 ºC.

10. Process according to any one of claims 1-9 which comprises the following steps:

- reacting isoallopregnanolone with a strong carboxylic acid <u>having a pka ≤ 3</u> under Mitsunobu conditions;
- precipitating the 3-carboxylic ester of allopregnanolone in a solvent system comprising water and an organic solvent;
- recrystallizing the precipitate of the 3-carboxylic ester of allopregnanolone in a non-polar solvent;
- subjecting the 3-carboxylic ester of allopregnanolone thus obtained to hydrolysis under neutral conditions, mild basic conditions or energetic basic conditions to afford allopregnanolone; and
- precipitating and recrystallizing thereby obtaining allopregnanolone with a total content of impurities I and II, in total, of 0.15% or below.
-

11. A 3-carboxylic ester of allopregnanolone <u>and a carboxylic acid having a pka ≤ 3, said ester</u> containing an amount of 5α-pregn-2-en-20-one of 0.5% or less.

~~12. Allopregnanolone containing an amount of 5α-pregn-2-en-20-one and 3α-hydroxy-5α,17α-pregnan-20-one, in total, of 0.15% or less.~~

~~13~~12. A 3-carboxylic ester of allopregnanolone selected from:

Pregnan-20-one, 3-(2,6-dinitrobenzoyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(2,4-dinitrobenzoyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(chloroacetyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(dichloroacetyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(trichloroacetyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(fluoroacetyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(difluoroacetyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(2-nitrobenzoyloxy)-, (3α,5α)-

Pregnan-20-one, 3-(cyanoacetyloxy)-, (3α,5α)-