CLAIMS

1. An injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol, phenoxyethanol, or a mixture thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0.

2. The injectable pharmaceutical composition according to claim 1, wherein the hydrophobic drug or its derivatives or its analogue is selected from: alfaxalone, propofol, meloxicam or carprofen, or derivatives and analogues of alfaxalone, propofol, meloxicam or carprofen.

3. The injectable pharmaceutical composition according to claim 1 or claim 2, wherein the cyclodextrin or cyclodextrin derivative is selected from: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins, sulfoalkyl ether β-cyclodextrins or a modified form thereof, or a mixture thereof.

4. The injectable pharmaceutical composition according to any one of claims 1 to 3, wherein the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

5. The injectable pharmaceutical composition according to any one of claims 1 to 4, wherein the at least one co-solvent is selected from: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

6. The injectable pharmaceutical composition according to any one of claims 1 to 5, wherein the buffer effective to stabilise the hydrophobic drug and provide a pH in the composition in a range of from about 4.0 to about 9.0 is present and is selected from: phosphate based, acid-phosphate based, and citrate based buffers.

7. The injectable pharmaceutical composition according to any one of claims 1 to 6, which further comprises at least one hydrophilic drug.

8. The injectable pharmaceutical composition according to any one of claims 1 to 7, wherein the at least one preservative is selected from the group consisting of: chlorocresol, benzethonium chloride, benzalkonium chloride, or a mixture thereof.

9. The injectable pharmaceutical composition according to any one of claims 1 to 8, wherein:

- the hydrophobic drug is alfaxalone;
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof; and
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

10. The injectable pharmaceutical composition according to any one of claims 1 to 8, wherein:

- the hydrophobic drug is propofol;
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof; and
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

11. The injectable pharmaceutical composition according to any one of claim 1 to 8, wherein:

- the hydrophobic drug is meloxicam;
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof; and
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

12. The injectable pharmaceutical composition according to any one of claims 1 to 8, wherein:

- the hydrophobic drug is carprofen;
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof; and
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

13. A method to produce an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products, wherein the method comprises:

- preparing a first composition by:
    a) dissolving a cyclodextrin or cyclodextrin derivative or a mixture thereof in water to form a solution;
    b) adding one or more hydrophobic drugs to the solution;
    c) optionally introducing additional water to fully dissolve the cyclodextrin or cyclodextrin derivative and the one or more hydrophobic drugs;
    d) optionally adding buffer salts;
    e) optionally adjusting the pH;
- preparing a second composition by:
    dissolving at least one preservative in one or more co-solvent(s), wherein the at least one preservative is selected from a group comprising: m-cresol, chlorocresol, methylparaben, ethylparaben, propylparaben, or butylparaben, their derivatives and salts, chlorobutanol, benzethonium chloride,

benzalkonium chloride, boric acid, benzyl alcohol, cetylpyridinium chloride, cetrimide, phenol, phenylethanol, phenoxyethanol, or a mixture thereof;

- and forming the injectable pharmaceutical composition by:
    a) combining the first and second compositions;
    b) optionally adding additional water to raise the combined composition to a required volume; and
    c) sterilising the combined composition.

14. The method according to claim 13, wherein the cyclodextrin or cyclodextrin derivative is selected from: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins, sulfoalkyl ether β-cyclodextrins or a modified form thereof, or a mixture thereof.

15. The method according to claim 13 or claim 14, wherein the one or more hydrophobic drugs are selected from: alfaxalone, propofol, meloxicam or carprofen.

16. The method according to any one of claims 13 to 15, wherein the one or more co-solvent(s) are selected from: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

17. The method according to any one of claims 13 to 16, wherein the buffer is effective to stabilise the hydrophobic drug and provide a pH in the first composition in a range of from about 4.0 to about 9.0 and is selected from: phosphate based, acid-phosphate based and citrate based buffers.

18. The method according to any one of claims 13 to 17, wherein the injectable pharmaceutical composition is sterilised by autoclaving.

19. The method according to any one of claims 13 to 18, wherein the injectable pharmaceutical composition further comprises at least one hydrophilic drug, wherein the at least one hydrophilic drug is added in the making of the first, second or the forming of the injectable pharmaceutical composition.

20. A method of preserving an injectable pharmaceutical composition comprising:
- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0

by including an effective amount of at least one preservative and at least one co-solvent in the injectable composition, wherein:

- the injectable pharmaceutical composition complies with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products; and
- the at least one preservative is selected from: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol, phenoxyethanol, or a mixture thereof.

21. The method according to claim 20, wherein the cyclodextrin or cyclodextrin derivative is selected from: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins, sulfoalkyl ether β-cyclodextrin or a modified form thereof, or a mixture thereof.

22. The method according to claim 20 or claim 21, wherein the hydrophobic drug is selected from: alfaxalone, propofol, meloxicam or carprofen.

23. The method according to any one of claims 20 to 22, wherein at least one preservative is selected from: chlorocresol, benzethonium chloride, benzalkonium chloride, or mixtures thereof.

24 The method according to any one of claims 20 to 23, wherein the at least one co-solvent is selected from: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

25. The method according to any one of claims 20 to 23, wherein the buffer is present and is effective to stabilise the hydrophobic drug and provide a pH in the first composition in a range of from about 4.0 to about 9.0 and is selected from: phosphate based, acid-phosphate based and citrate based buffers.

26. The method according to any one of claims 20 to 25, wherein the injectable pharmaceutical composition further comprises at least one hydrophilic drug.

27. Use of at least one co-solvent and at least one preservative to preserve an injectable pharmaceutical composition comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

by introducing the at least one co-solvent and the at least one preservative into the composition, wherein:

- the injectable pharmaceutical composition complies with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products; and
- the at least one preservative is selected from: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol, phenoxyethanol, or a mixture thereof.

28. The use according to claim 27, wherein the cyclodextrin or cyclodextrin derivative is selected from: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins, sulfoalkyl ether β-cyclodextrins or a modified form thereof, or a mixture thereof.

29. The use according to claim 27 or claim 28, wherein the hydrophobic drug is selected from: alfaxalone, propofol, meloxicam or carprofen.

30. The use according to any one of claims 27 to 29, wherein at least one preservative is selected from: chlorocresol, benzalkonium chloride, boric acid, or mixtures thereof.

31. The use according to any one of claims 27 to 30, wherein the at least one co-solvent is selected from: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

32. The use according to any one of claims 27 to 31, wherein the buffer is present and is effective to stabilise the hydrophobic drug and provide a pH in the injectable pharmaceutical composition in a range of from about 4.0 to about 9.0 and is selected from: phosphate based, acid-phosphate based and citrate based buffers.

33. The use according to any one of claims 27 to 32, wherein the injectable pharmaceutical composition further comprises at least one hydrophilic drug.

34. Use of an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol, phenoxyethanol, or a mixture thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

in the preparation of a medicament for treating a non-human animal.

35. The use according to claim 34, wherein the treating a non-human animal is for at least one of the purposes of: anaesthetising the non-human animal, alleviating pain, or alleviating inflammation.

36. The use according to claim 34 or claim 35, wherein the hydrophobic drug is selected from: alfaxalone, propofol, meloxicam or carprofen.

37. The use according to any one of claims 34 to 36, wherein the cyclodextrin or cyclodextrin derivative is selected from: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins, sulfoalkyl ether β-cyclodextrins or a modified form thereof, or a mixture thereof.

38. The use according to any one of claims 34 to 37, wherein the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

39. The use according to any one of claims 34 to 38, wherein the at least one co-solvent is selected from: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

40. The use according to any one of claims 34 to 39, wherein:
- the hydrophobic drug is alfaxalone;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

41. The use according to any one of claims 34 to 39, wherein:
- the hydrophobic drug is propofol;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and

- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

42. The use according to any one of claims 34 to 39, wherein:
- the hydrophobic drug is meloxicam;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

43. The use according to any one of claims 34 to 39, wherein:
- the hydrophobic drug is carprofen;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

44. Use of an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products comprising:
- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol, phenoxyethanol, or a mixture thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

in the preparation of a medicament for treating a human being.

45. The use according to claim 44, wherein the treating a human being is for the purpose of anaesthetising the human being.

46. The use according to claim 44 or claim 45, wherein the hydrophobic drug is selected from: alfaxalone, propofol, meloxicam or carprofen.

47. The use according to any one of claims 44 to 46, wherein the cyclodextrin or cyclodextrin derivative is selected from: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins, sulfoalkyl ether β-cyclodextrins or a modified form thereof, or a mixture thereof.

48. The use according to any one of claims 44 to 47, wherein the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

49. The use according to any one of claims 44 to 48, wherein the at least one co-solvent is selected from: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

50. The use according to any one of claims 44 to 49, wherein:
- the hydrophobic drug is alfaxalone;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

51. The use according to any one of claims 44 to 49, wherein:
- the hydrophobic drug is propofol;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

52. The use according to any one of claims 44 to 49, wherein:

- the hydrophobic drug is meloxicam;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

53. The use according to any one of claims 44 to 49, wherein:

- the hydrophobic drug is carprofen;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal, tetraglycol, or a mixture thereof.

What is claimed is:

1. An injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from the group consisting of: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0.

2. The injectable pharmaceutical composition according to claim 1, wherein the hydrophobic drug is selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen, and derivatives and analogs of alfaxalone, propofol, meloxicam and carprofen.

3. The injectable pharmaceutical composition according to claim 1 or claim 2, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

4. The injectable pharmaceutical composition according to any one of claims 1 to 3, wherein the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

5. The injectable pharmaceutical composition according to any one of claims 1 to 4, wherein the at least one co-solvent is selected from the group consisting of: ethanol, glycerine, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

6. The injectable pharmaceutical composition according to any one of claims 1 to 5, wherein the at least one preservative is selected from the group consisting of: chlorocresol, benzethonium chloride and benzalkonium chloride, and a mixture thereof.

7. The injectable pharmaceutical composition according to any one of claims 1 to 6, wherein:

- the hydrophobic drug is alfaxalone;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

8. The injectable pharmaceutical composition according to any one of claims 1 to 6, wherein:

- the hydrophobic drug is propofol;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol,

glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

9. The injectable pharmaceutical composition according to any one of claims 1 to 6, wherein:

- the hydrophobic drug is meloxicam;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

10. The injectable pharmaceutical composition according to any one of claims 1 to 6, wherein:

- the hydrophobic drug is carprofen;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

11. The injectable pharmaceutical composition according to any one of claims 1 to 10, wherein the buffer effective to stabilise the hydrophobic drug and provide a pH in the composition in a range of from about 4.0 to about 9.0 is present and is selected from the group consisting of: phosphate based, acid-phosphate based, and citrate based buffers.

12. The injectable pharmaceutical composition according to any one of claims 1 to 11, which further comprises at least one hydrophilic drug.

13. A method to produce an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products, wherein the method comprises:

- preparing a first composition by:
  - a) dissolving a cyclodextrin or cyclodextrin derivative or a mixture thereof in water to form a solution;
  - b) adding one or more hydrophobic drugs to the solution;
  - c) optionally introducing additional water to fully dissolve the cyclodextrin or cyclodextrin derivative and the one or more hydrophobic drugs;
  - d) optionally adding buffer salts; and
  - e) optionally adjusting the pH;
- preparing a second composition by:

  dissolving at least one preservative in one or more co-solvent(s), wherein the preservative is selected from the group consisting of: m-cresol, chlorocresol, methylparaben, ethylparaben, propylparaben, and butylparaben, and their derivatives and salts, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, benzyl alcohol, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof;
- and forming the injectable pharmaceutical composition by:
  - a) combining the first and second compositions;
  - b) optionally adding additional water to raise the combined composition to a required volume; and
  - c) sterilising the combined composition.

14. The method according to claim 13, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-

cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

15. The method according to claim 13 or claim 14, wherein the one or more hydrophobic drugs are selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen.

16. The method according to any one of claims 13 to 15, wherein the one or more co-solvent(s) are selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

17. The method according to any one of claims 13 to 16, wherein the buffer is present and is effective to stabilise the hydrophobic drug and provide a pH in the first composition in a range of from about 4.0 to about 9.0 and is selected from the group consisting of: phosphate based, acid-phosphate based and citrate based buffers.

18. The method according to any one of claims 13 to 17, wherein the injectable pharmaceutical composition is sterilised by autoclaving.

19. The method according to any one of claims 13 to 18, wherein the pharmaceutical composition further comprises at least one hydrophilic drug, wherein the at least one hydrophilic drug is added in the making of the first, second or the forming of the injectable pharmaceutical composition.

20. A method of preserving an injectable pharmaceutical composition comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug and

- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

by including an effective amount of at least one preservative and at least one co-solvent in the composition, wherein:

- the injectable pharmaceutical composition complies with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products; and
- the at least one preservative is selected from the group consisting of: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof.

21. The method according to claim 20, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

22. The method according to claim 20 or claim 21, wherein the hydrophobic drug is selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen.

23. The method according to any one of claims 20 to 22, wherein the at least one preservative is selected from the group consisting of: chlorocresol, benzethonium chloride and benzalkonium chloride, and mixtures thereof.

24. The method according to any one of claims 20 to 23, wherein the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

25. The method according to any one of claims 20 to 24, wherein the buffer is effective to stabilise the hydrophobic drug and provide a pH in the first composition in a range of from about 4.0 to about 9.0 and is selected from the group consisting of: phosphate based, acid-phosphate based and citrate based buffers.

26. The method according to any one of claims 20 to 25, wherein the pharmaceutical composition further comprises at least one hydrophilic drug.

27. Use of at least one co-solvent and at least one preservative to preserve an injectable pharmaceutical composition comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

by introducing the at least one co-solvent and the at least one preservative into the composition, wherein:

- the injectable pharmaceutical composition complies with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products; and
- the at least one preservative is selected from the group consisting of: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride,boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof.

28. The use according to claim 27, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

29. The use according to claim 27 or claim 28, wherein the hydrophobic drug is selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen.

30. The use according to any one of claims 27 to 29, wherein the at least one preservative is selected from the group consisting of: chlorocresol, benzethonium chloride and benzalkonium chloride, and mixtures thereof.

31. The use according to any one of claims 27 to 30, wherein the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

32. The use according to any one of claims 27 to 31, wherein:
- the hydrophobic drug is alfaxalone;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

33. The use according to any one of claims 27 to 31, wherein:
- the hydrophobic drug is propofol;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol,

glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

34. The use according to any one of claims 27 to 31, wherein:
- the hydrophobic drug is meloxicam;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

35. The use according to any one of claims 27 to 31, wherein:
- the hydrophobic drug is carprofen;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

36. The use according to any one of claims 27 to 35, wherein the buffer is present and is effective to stabilise the hydrophobic drug and provide a pH in the first composition in a range of from about 4.0 to about 9.0 and is selected from the group consisting of: phosphate based, acid-phosphate based and citrate based buffers.

37. The use according to any one of claims 27 to 36, wherein the pharmaceutical composition further comprises at least one hydrophilic drug.

38. A use of an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia

2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products, the composition comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from the group consisting of: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

for at least one of : anaesthetising a non-human animal, alleviating pain in a non-human animal and alleviating inflammation in a non-human animal.

39. The use according to claim 38, wherein the hydrophobic drug is selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen.

40. The use according to claim 38 or claim 39, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

41. The use according to any one of claims 38 to 40, wherein the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin.

42. The use according to any one of claims 38 to 41, wherein the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

43. The use according to any one of claims 38 to 42, wherein the at least one preservative is selected from the group consisting of: chlorocresol, benzethonium chloride and benzalkonium chloride, and a mixture thereof.

44. The use according to any one of claims 38 to 42, wherein:
- the hydrophobic drug is alfaxalone;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

45. The use according to any one of claims 38 to 42, wherein:
- the hydrophobic drug is propofol;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

46. The use according to any one of claims 38 to 42, wherein:
- the hydrophobic drug is meloxicam;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

47. The use according to any one of claims 38 to 42, wherein:

- the hydrophobic drug is carprofen;
- the cyclodextrin or cyclodextrin derivative is 2-hydroxypropyl-β-cyclodextrin; and
- the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

48. A use of an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products, the composition comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from the group consisting of: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0, for the purpose of anaesthetising the human being.

49. The use according to claim 48, wherein the hydrophobic drug is selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen.

50. The use according to claim 48 or claim 49, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-

cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

51. The use according to any one of claims 48 to 50, wherein the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.

52. Use of an injectable pharmaceutical composition complying with the European Pharmacopoeia 2011 Test for Efficacy of Antimicrobial Preservation, satisfying at least the B criteria for parenterals, and the United States Pharmacopeia 2011 Guidelines for Antimicrobial Effectiveness Testing for Category 1 (injectable) products comprising:

- water,
- one or more water soluble complexes, each comprising a cyclodextrin or a cyclodextrin derivative and a hydrophobic drug,
- at least one preservative selected from the group consisting of: m-cresol, chlorocresol, chlorobutanol, benzethonium chloride, benzalkonium chloride, boric acid, cetylpyridinium chloride, cetrimide, phenol, phenylethanol and phenoxyethanol, and mixtures thereof,
- at least one co-solvent and
- optionally a buffer effective to provide a pH in the composition in a range of from about 4.0 to about 9.0,

in the preparation of a medicament for the purpose of anaesthetising a human being.

53. The use according to claim 52, wherein the hydrophobic drug is selected from the group consisting of: alfaxalone, propofol, meloxicam and carprofen.

54. The use according to claim 52 or claim 53, wherein the cyclodextrin or cyclodextrin derivative is selected from the group consisting of: α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, methyl substituted cyclodextrins, ethyl substituted

cyclodextrins, hydroxyalkyl substituted cyclodextrins, 2-hydroxypropyl-β-cyclodextrin, alkyl ether cyclodextrins, branched cyclodextrins, cationic cyclodextrins, quaternary ammonium cyclodextrins, anionic cyclodextrins, amphoteric cyclodextrins and sulfoalkyl ether β-cyclodextrins, and a modified form thereof, and mixtures thereof.

55. The use according to any one of claims 52 to 54, wherein the at least one co-solvent is selected from the group consisting of: ethanol, glycerin, propylene glycol, isopropyl alcohol, glycerol formal and tetraglycol, and mixtures thereof.