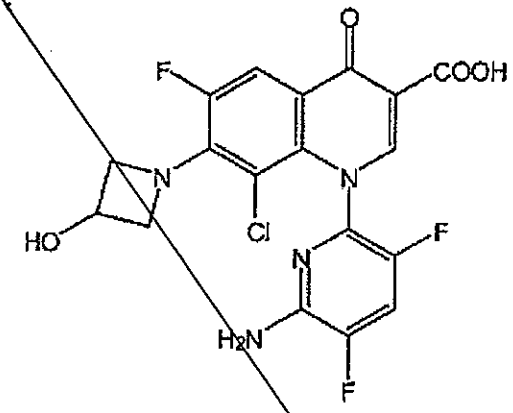
WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising

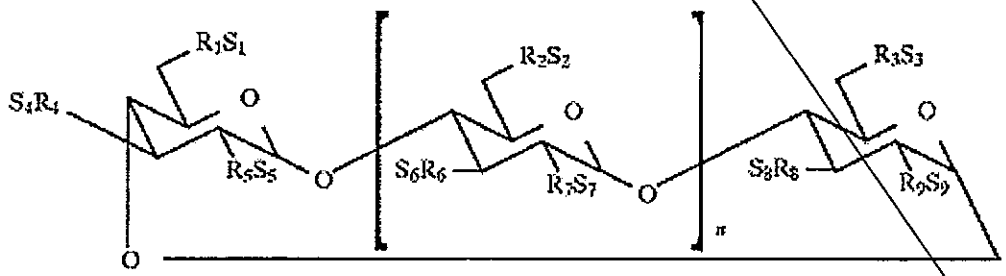
(a) a quinolone carboxylic acid derivative or a pharmaceutically acceptable salt or ester thereof, wherein said quinolone carboxylic acid derivative corresponds to the following compound (A)



(A)

and

(b) a cyclodextrin; wherein said cyclodextrin is selected from a beta-cyclodextrin and a sulfoalkyl ether cyclodextrin of Formula 1:



Formula 1

wherein n is 4, 5 or 6;

R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 in Formula 1 are each, independently, O^- or a O-(C_{2-6} alkylene)-SO_3^- group, and at least one of R_1 and R_2 is, independently, said O-(C_{2-6} alkylene)-SO_3^- group; and

S_1, S_2, S_3, S_4, S_5, S_6, S_7, S_8 and S_9 are each, independently, a pharmaceutically acceptable cation, and wherein said composition shows an absence of underivatized cyclodextrin as measured by thin-layer chromatography.

2. A pharmaceutical composition according to claim 1, wherein said cyclodextrin is a beta-cyclodextrin and said beta-cyclodextrin is a hydroxyalkyl-beta-cyclodextrin.

3. A pharmaceutical composition according to claim 2 wherein said hydroxyalkyl-beta-cyclodextrin is a hydroxypropyl-beta-cyclodextrin.

4. A pharmaceutical composition according to claim 1, wherein said cyclodextrin is a beta-cyclodextrin corresponding to the following formula (3)

(beta-cyclodextrin)-OR

(3)

wherein R is hydroxypropyl, the beta-cyclodextrin ether having a water-solubility of more than 1.8 g in 1000 ml water.

5. A pharmaceutical composition according to claim 3 wherein said hydroxypropyl beta-cyclodextrin corresponds to the CAS Registry Number 128446-35-5.

6. A pharmaceutical composition of claim 1, wherein the cyclodextrin is a sulfoalkyl ether cyclodextrin of Formula 1, and at least one of R_4, R_6 and R_8 is, independently, said O-(C_{2-6} -alkylene)-SO_3^- group; and R_5, R_7 and R_9 are each $-O^-$.

7. A pharmaceutical composition according to claim 1, wherein said cyclodextrin is a sulfoalkyl ether cyclodextrin, and said sulfoalkyl ether cyclodextrin is sulfobutyl ether beta-cyclodextrin.

8. A pharmaceutical composition according to claim 6 wherein said sulfoalkyl ether beta-cyclodextrin corresponds to the CAS Registry Number 194615-04-8.

9. A pharmaceutical composition according to claim 1 wherein said quinolone carboxylic acid derivative is a D-glucitol, l-deoxy-l-(methylamino)-, l-(6-amino-3,5-difluoro-2-pyridinyl)-8-chloro-6-fluoro-l ,4-dihydro-7-(3-hydroxy-1 -azetidinyl)-4-oxo-3-quinolinecarboxylate (salt).

10. A pharmaceutical composition according to claim 1 wherein said quinolone carboxylic acid derivative is D-glucitol, l-deoxy-l-(methylamino)-, l-(6-amino-3,5-difluoro-2-pyridinyl)-8-chloro-6-fluoro-1,4-dihydro-7-(3 -hydroxy-1 -azetidinyl)-4-oxo-3 -quinolinecarboxylate trihydrate (salt).

11. A pharmaceutical composition according to claim 1 further comprising a chelating agent.

12. A pharmaceutical composition according to claim 11 wherein said chelating agent is disodium EDTA.

13. A pharmaceutical composition according to claim 1 further comprising a polyhydroxyamine compound.

14. A pharmaceutical composition according to claim 13 wherein said polyhydroxyamine compound is meglumine.

15. A pharmaceutical composition according to claim 1 wherein said quinolone carboxylic acid derivative has a measurable improvement in solubility compared to the quinolone carboxylic acid derivative in water, and/or the composition has improved stability, and/or the composition provides a measurable enhancement in venous toleration.

16. A pharmaceutical composition comprising

(a) from about 100 mg to about 500 mg of delafloxacin meglumine,

(b) from about 15 mg to about 125 meglumine,

(c) from about 500 mg to about 5000 mg of sulfobutyl ether beta-cyclodextrin corresponding to the CAS Registry Number 194615-04-8, and

(d) from 0 mg to about 4 mg disodium EDTA.

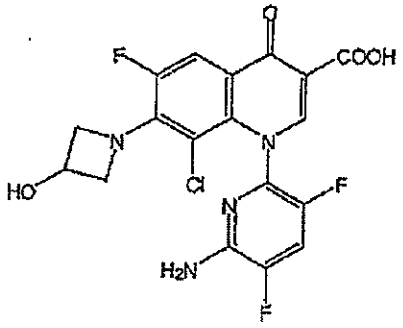
17. A pharmaceutical composition according to claim 16 which is in the form of a lyophile.

18. Use of a composition according to claim 1 in the manufacture of a medicament for treating, preventing, or reducing the risk of a bacterial infection.

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising

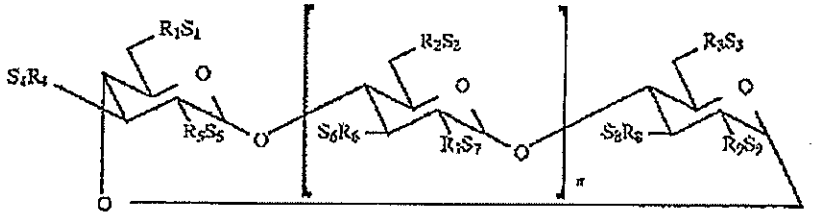
(a) a quinolone carboxylic acid derivative or a pharmaceutically acceptable salt or ester thereof, wherein said quinolone carboxylic acid derivative corresponds to the following compound (A)



(A)

and

(b) a cyclodextrin; wherein said cyclodextrin is selected from a beta-cyclodextrin and a sulfoalkyl ether cyclodextrin of Formula 1:



Formula I

wherein n is 4, 5 or 6;

R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 in Formula 1 are each, independently, O^- or a O-(C_{2-6} alkylene)-SO_3^- group, and at least one of R_1 and R_2 is, independently, said O-(C_{2-6} alkylene)-SO_3^- group; and

S_1, S_2, S_3, S_4, S_5, S_6, S_7, S_8 and S_9 are each, independently, a pharmaceutically acceptable cation, and wherein said composition shows an absence of underivatized cyclodextrin as measured by thin-layer chromatography.

2. A pharmaceutical composition according to claim 1, wherein said cyclodextrin is a beta-cyclodextrin and said beta-cyclodextrin is a hydroxyalkyl-beta-cyclodextrin.

3. A pharmaceutical composition according to claim 2 wherein said hydroxyalkyl-beta-cyclodextrin is a hydroxypropyl-beta-cyclodextrin.

4. A pharmaceutical composition according to claim 1, wherein said cyclodextrin is a beta-cyclodextrin corresponding to the following formula (3)

(beta-cyclodextrin)-OR

(3)

wherein R is hydroxypropyl, the beta-cyclodextrin ether having a water-solubility of more than 1.8 g in 1000 ml water.

5. A pharmaceutical composition according to claim 3 wherein said hydroxypropyl beta-cyclodextrin corresponds to the CAS Registry Number 128446-35-5.

6. A pharmaceutical composition of claim 1, wherein the cyclodextrin is a sulfoalkyl ether cyclodextrin of Formula 1, and at least one of R_4, R_6 and R_8 is, independently, said O-(C_{2-6}-alkylene)-SO_3^- group; and R_5, R_7 and R_9 are each -O^-.

7. A pharmaceutical composition according to claim 1, wherein said cyclodextrin is a sulfoalkyl ether cyclodextrin, and said sulfoalkyl ether cyclodextrin is sulfobutyl ether beta-cyclodextrin.

8. A pharmaceutical composition according to claim 6 wherein said sulfoalkyl ether beta-cyclodextrin corresponds to Captisol.

9. A pharmaceutical composition according to claim 1 wherein said quinolone carboxylic acid derivative is a D-glucitol, l-deoxy-l-(methylamino)-, l-(6-amino-3,5-difluoro-2-pyridinyl)-8-chloro-6-fluoro-l ,4-dihydro-7-(3-hydroxy-1 -azetidinyl)-4-oxo-3-quinolinecarboxylate (salt).

10. A pharmaceutical composition according to claim 1 wherein said quinolone carboxylic acid derivative is D-glucitol, l-deoxy-l-(methylamino)-, l-(6-amino-3,5-difluoro-2-pyridinyl)-8-chloro-6-fluoro-1,4-dihydro-7-(3 -hydroxy-1 -azetidinyl)-4-oxo-3 -quinolinecarboxylate trihydrate (salt).

11. A pharmaceutical composition according to claim 1 further comprising a chelating agent.

12. A pharmaceutical composition according to claim 11 wherein said chelating agent is disodium EDTA.

13. A pharmaceutical composition according to claim 1 further comprising a polyhydroxyamine compound.

14. A pharmaceutical composition according to claim 13 wherein said polyhydroxyamine compound is meglumine.

15. A pharmaceutical composition comprising
(a) from 100 mg to 500 mg of delafloxacin meglumine,

(b) from 15 mg to 125 meglumine,

(e) from 500 mg to 5000 mg of sulfobutyl ether beta-cyclodextrin corresponding to Captisol, and

(d) from 0 mg to 4 mg disodium EDTA.

16. A pharmaceutical composition according to claim 15 which is in the form of a lyophile.

17. Use of a composition according to claim 1 in the manufacture of a medicament for treating, preventing, or reducing the risk of a bacterial infection.