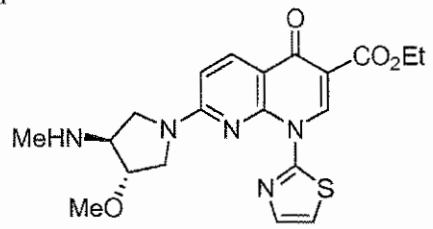
WHAT IS CLAIMED:

1. A process for preparing a substantially pure SNS-595 substance, comprising:

(a) reacting Compound 3



3

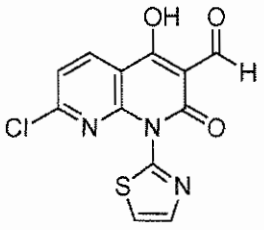
with a first aqueous base followed by neutralizing to obtain a primary SNS-595 hydrate;

(b) dehydrating the primary SNS-595 hydrate from step (a) and reacting the dehydrated product with a second aqueous base followed by neutralizing to obtain a secondary SNS-595 hydrate; and

(c) dehydrating the secondary SNS-595 hydrate obtained in step (b) to obtain the substantially pure SNS-595 substance.

2. The process of claim 1, wherein the first and second aqueous bases are ethanol; the neutralizations of steps (a) and (b) are accomplished with acetic acid; and the dehydration of steps (b) and (c) are accomplished with ethanol.

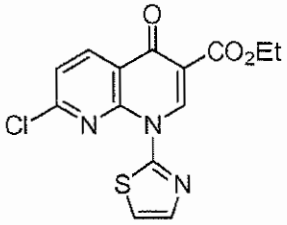
3. The process of claim 2, wherein the substantially pure SNS-595 substance obtained from step (c) comprises about 0 to 0.01% Compound 4



4

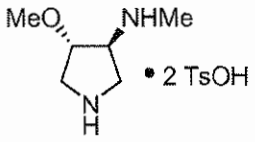
based on total weight of the substantially pure SNS-595 substance.

4. The process of claim 1, wherein Compound 3 is obtained by reaction of Compound 1



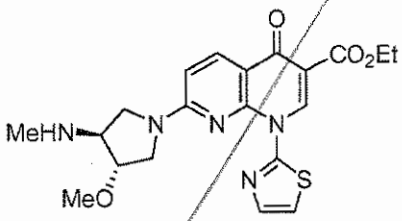
1

with Compound 2



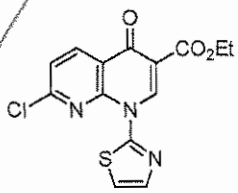
2.

5. A process for preparing substantially pure Compound 3



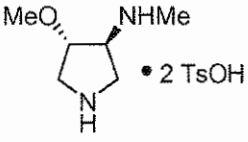
3,

comprising reacting Compound 1



1

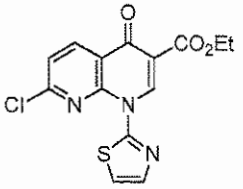
with Compound 2



2

in the presence of N,N-diisopropylethylamine and water to obtain substantially pure Compound 3.

6. The process of claim 5, wherein the substantially pure Compound 3 obtained comprises from 0 to about 0.1% Compound 1

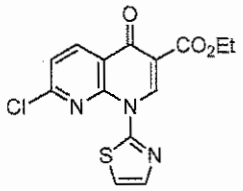


1

based on total weight of substantially pure Compound 3.

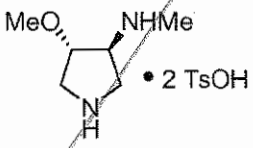
7. A process for preparing a substantially pure SNS-595 substance, comprising:

(a) reacting Compound 1



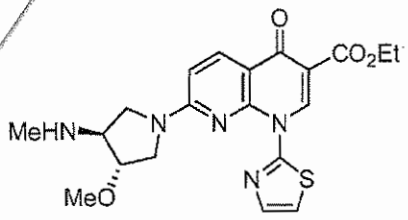
1

with Compound 2



2

in the presence of N,N-diisopropylethylamine and water to obtain substantially pure Compound 3

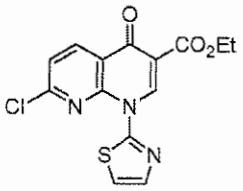


3;

(b) reacting the substantially pure Compound 3 with an aqueous base followed by neutralizing to obtain a primary SNS-595 hydrate; and

(c) dehydrating the primary SNS-595 hydrate obtained in step (a) to obtain the substantially pure SNS-595 substance.

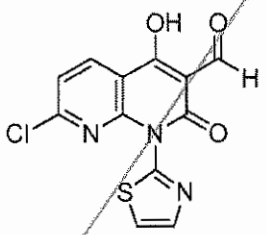
8. The process of claim 7, wherein the substantially pure Compound 3 obtained comprises about 0 to 0.1% Compound 1



1

based on total weight of the substantially pure Compound 3.

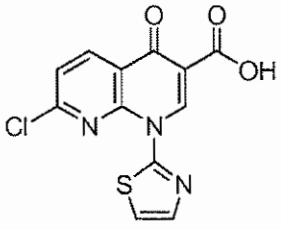
9. The process of claim 7, wherein the substantially pure SNS-595 substance obtained from step (c) comprises about 0 to 0.01% Compound 4



4

based on total weight of the substantially pure SNS-595 substance.

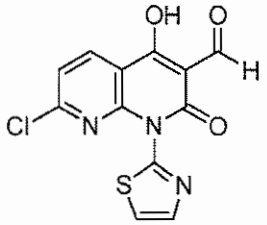
10. The process of claim 7, wherein the substantially pure SNS-595 substance obtained from step (b) comprises about 0 to 0.02% Compound 5



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based on total weight of the substantially pure SNS-595 substance.

11. A composition comprising substantially pure SNS-595 substance, wherein the substantially pure SNS-595 substance comprises about 0 to 0.03% Compound 4

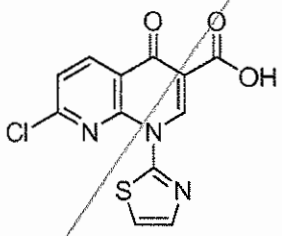


4

based on total weight of the substantially pure SNS-595 substance.

12. The composition of claim 11, wherein the substantially pure SNS-595 substance comprises about 0 to 0.01% Compound 4, at the time of production of the composition.

13. A composition comprising SNS-595 and about 0 to 0.04 wt% Compound 5



5.

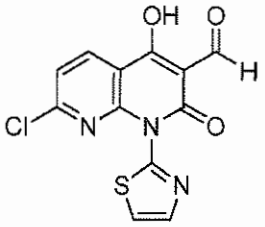
14. The composition of claim 13, wherein the substantially pure SNS-595 substance comprises about 0 to 0.02% Compound 5, at the time of production of the composition.

15. A composition comprising SNS-595 and water, wherein about 100 mg of SNS-595 is present for every 10 mL of the composition, the composition is essentially free of visible particles, and the composition is stable with respect to visible particles.

16. The composition of claim 15, wherein the composition consists essentially of 100 mg SNS-595, 450 mg D-sorbitol, water, and methanesulfonic acid, wherein the pH of

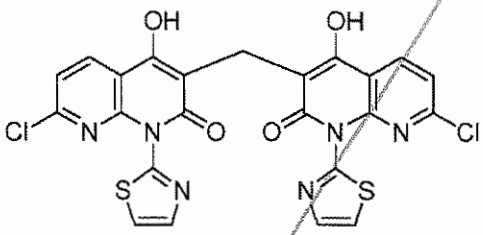
the composition is about 2.5, and wherein the water is present in an amount to provide a total composition volume of 10 mL.

17. The composition of claim 11, wherein the composition is stable with respect to visible particles when contacted with a compound capable of transforming Compound 4



4

to Compound 6

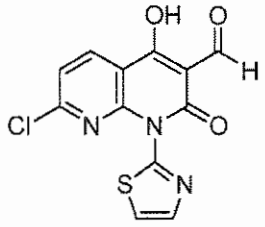


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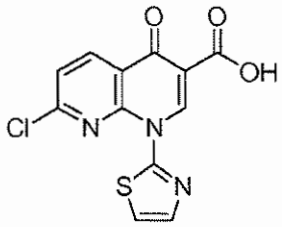
18. The composition of claim 15, wherein the composition is stable for 1, 3, 6, 9, 12, 18, 24, 36, or 42 months.

19. A composition comprising SNS-595 and water, wherein about 100 mg of SNS-595 is present for every 10 mL of the composition, and the composition is stable with respect to quantity of sub-visible particles therein.

20. A composition consisting essentially of SNS-595 and 0.03 wt% or less Compound 4

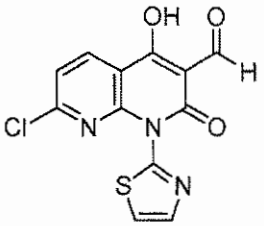


21. A composition consisting essentially of SNS-595 and 0.04 wt% or less Compound 5

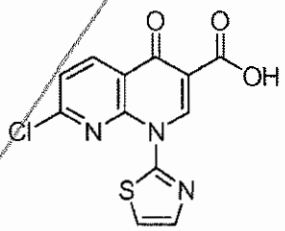


5.

22. A composition comprising SNS-595 and 0.07 wt% or less total Compound 4 and Compound 5

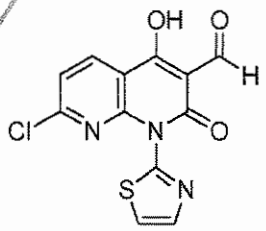


4



5.

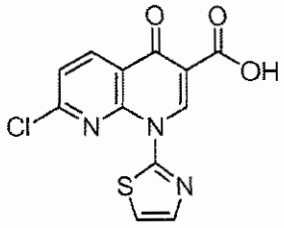
23. A composition comprising SNS-595 and 0.3 mg or less Compound 4



4

per gram of SNS-595.

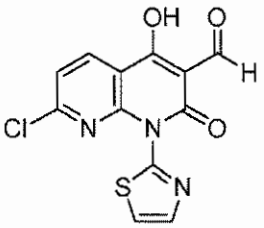
24. A composition comprising SNS-595 and 0.4 mg or less Compound 5



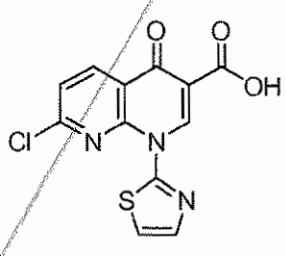
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per gram of SNS-595.

25. A composition comprising SNS-595 and 0.7 mg or less total Compound 4 and Compound 5



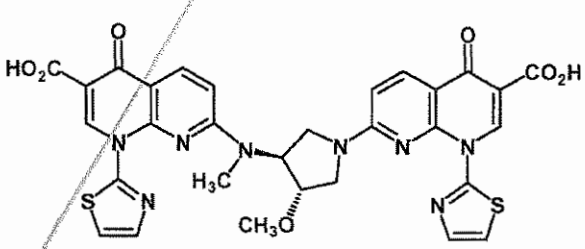
4



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per gram of SNS-595.

26. A composition comprising SNS-595 and less than or equal to 0.15% of compound 7

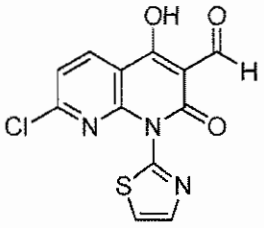


7

based on total weight of the composition.

27. An aqueous solution consisting essentially of:

(a) 10 g of a substantially pure SNS-595 substance comprising SNS-595 and Compound 4 wherein the substantially pure SNS-595 substance contains 3 mg or less Compound 4 per gram



4

(b) 4.5 g of sorbitol: and

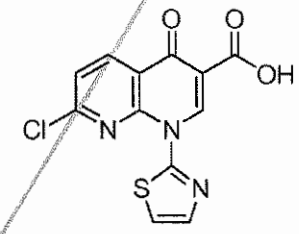
(c) sufficient methanesulfonic acid to provide a pH of 2.5;

per 100 mL of the solution.

28. A product comprising a container containing 10 mL of the solution of claim 25.

29. An aqueous solution consisting essentially of:

(a) 10 g of a substantially pure SNS-595 substance consisting of SNS-595 and Compound 5



5

wherein the substantially pure SNS-595 substance contains 4 mg or less Compound 5 per gram;

(b) 4.5 g of sorbitol: and

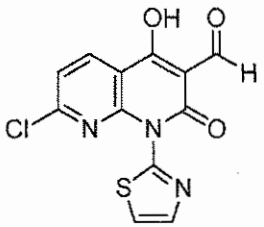
(c) sufficient methanesulfonic acid to provide a pH of 2.5;

per 100 mL of the solution.

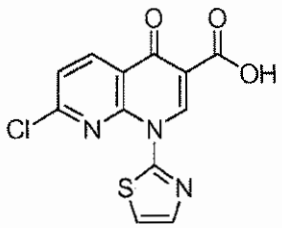
30. A product comprising a container containing 10 mL of the solution of claim 27.

31. An aqueous solution consisting essentially of:

(a) 10 g of a substantially pure SNS-595 substance consisting of SNS-595, Compound 4 and Compound 5



4



5

wherein the substantially pure SNS-595 substance contains 7 mg or less total Compound 4 and Compound 5 combined per gram;

(b) 4.5 g of sorbitol: and

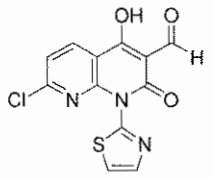
(c) sufficient methanesulfonic acid to provide a pH of 2.5;

per 100 mL of the solution.

32. A product comprising a container containing 10 mL of the solution of claim 29.

WHAT IS CLAIMED:

1. A substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance comprising (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid, or a salt or solvate thereof, and 0 to 0.02% Compound 4



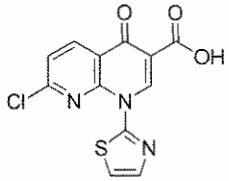
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based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance, and

wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance comprises less than 1.0% of any other individual compound, based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

2. A composition comprising the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance of claim 1.

3. The composition of claim 2, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance further comprises 0 to 0.02% Compound 5



5

based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

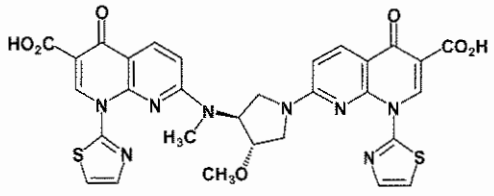
4. The composition of claim 3, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance comprises 0 to 0.03% of Compound 4 and Compound 5 combined based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

5. The composition of claim 2, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance comprises 0 to 0.01% Compound 4 based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

6. The composition of claim 2 which is an aqueous solution.

7. The composition of claim 6, wherein the composition further comprises methanesulfonic acid in an amount to provide the solution a pH of 2.5.

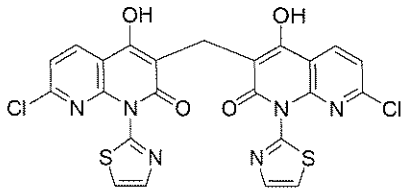
8. The composition of claim 2, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance further comprises 0 to 0.1% Compound 7



7

based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

9. The composition of claim 2 which is an aqueous solution, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance further comprises 0 to 0.02% Compound 6



6

based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

10. The composition of claim 9, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance comprises 0 to 0.01% Compound 6 based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.

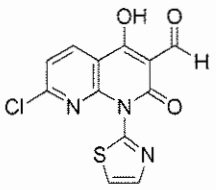
11. The composition of claim 9, wherein the composition is essentially free of sub-visible and visible particles for at least one month starting from the time of production.

12. The composition of claim 2 comprising (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid as a hydrate.

13. The composition of claim 2 which is an aqueous solution, wherein about 100 mg of substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance, or a salt or solvate thereof, is present for every 10 mL of the composition, and wherein the composition is stable at 3 months after production, preferably wherein the composition has not more than 1000 particles $\geq$ 10 microns per 10 mL of the composition.

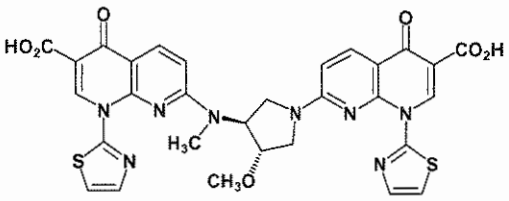
14. The composition of claim 2 which is an aqueous solution, wherein the aqueous solution consists essentially of 100 mg substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance, or a salt or solvate thereof, 450 mg sorbitol, water, and methanesulfonic acid, wherein the methanesulfonic acid is present in an amount to adjust the pH to 2.5pH of the aqueous solution is about 2.5, and wherein the water is present in an amount to provide a total solution volume of 10 mL.

15. The composition of claim 2 which is a composition consisting essentially of (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid, or a salt or solvate thereof, 0 to 0.02 wt% Compound 4



4

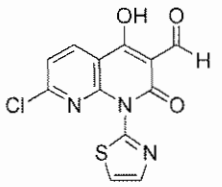
and 0 to 0.1 wt% Compound 7



7

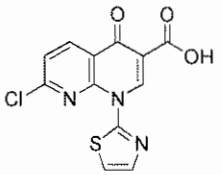
based on total weight of the composition.

16. The composition of claim 2 which is a composition consisting essentially of (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid, or a salt or solvate thereof, 0 to 0.02 wt% Compound 4



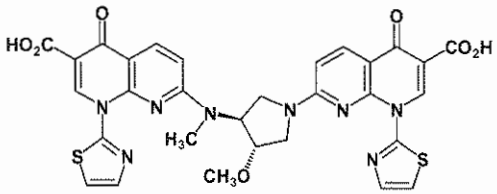
4,

0 to 0.02 wt% Compound 5



5,

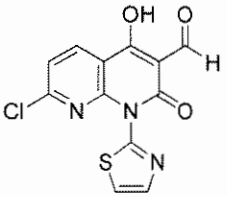
and 0 to 0.1 wt% Compound 7



7

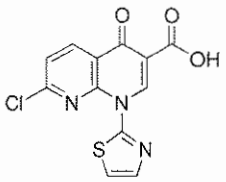
based on total weight of the composition.

17. The composition of claim 2 which is an aqueous solution, wherein the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance consists essentially of (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid, or a salt or solvate thereof, 0 to 0.02 wt% Compound 4



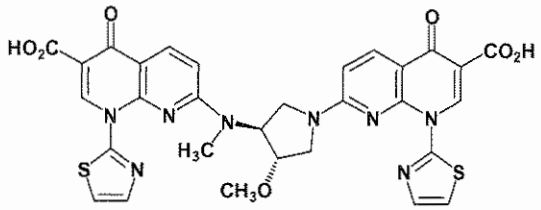
4,

0 to 0.02 wt% Compound 5



5,

and 0 to 0.1 wt% Compound 7



7,

based on total weight of the substantially pure (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance.