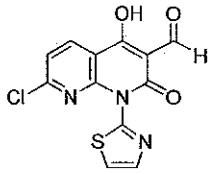
3. SUMMARY

[008a] In one aspect, the present invention refers to an aqueous solution comprising a (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid composition, wherein the composition 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, and 0 to 0.02% Compound 4



4

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

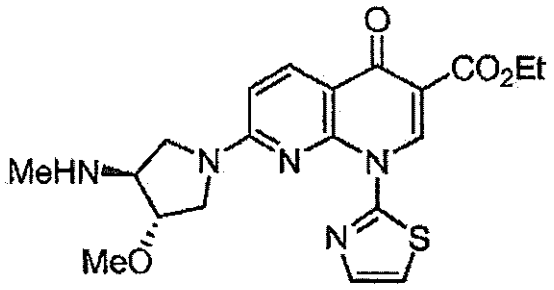
the aqueous solution is stable at 3 months after production or comprises not more than 1000 particles $\geq$ 10 microns per 10 mL of the aqueous solution, wherein 100 mg of (+)-1,4-dihydro-7-[(3S,4S)-3-methoxy-4-(methylamino)-1-pyrrolidinyl]-4-oxo-1-(2-thiazolyl)-1,8-naphthyridine-3-carboxylic acid substance,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

[008b] In another aspect, the present invention refers to a vial comprising the aqueous solution of the present invention.

[0009] Processes are provided that can yield a substantially pure SNS-595 substance. In addition, the processes can be scaled up to commercial manufacturing of substantially pure SNS-595 substance.

[0010] In some examples, processes are provided for preparing a substantially pure SNS-595 substance, comprising:

(a) reacting Compound 3



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

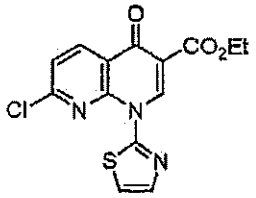
(b) dehydrating the primary SNS-595 hydrate from step (a) and reacting the dehydrated product with a second aqueous base followed by neutralizing to obtain a secondary SNS-595 hydrate; and

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

[0011] In some cases, it may be desirable to react the substantially pure SNS-595 substance obtained in step (c) with a further aqueous base, neutralize, and then dehydrate to further improve the purity of the substantially pure SNS-595 product. The first aqueous base, the second aqueous base, and the further aqueous base(s) can be the same or different. Likewise, the acids employed during the neutralization steps may be the same or different. Recycling of the substantially pure SNS-595 substance through the described steps of treatment with aqueous base, neutralization, and dehydration may be performed a plurality of times to sequentially further purify the SNS-595 substance until a substantially pure SNS-595 substance of a desired level of purity is obtained.

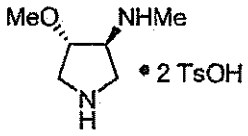
[0012] In some examples, processes are provided for preparing a substantially pure SNS-595 substance, comprising:

(a) reacting Compound **1**



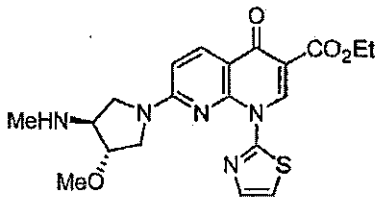
1

with Compound **2**



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



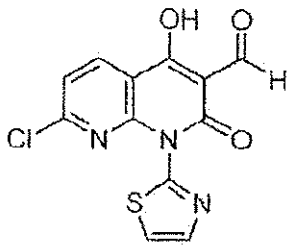
3;

and

(b) reacting Compound **3** with an aqueous base to form the substantially pure SNS-595 substance.

[0013] In some examples, provided herein are compositions comprising

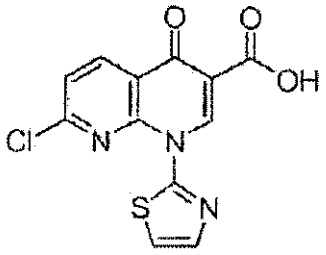
substantially pure SNS-595 substance, wherein tbe substantially pure SNS-595 substance comprises about 0 to 0.01% Compound **4**



4

at the time of production of the compositions, based on total weight of the substantially pure SNS-595 substance.

[0014] In some examples, provided herein are compositions comprising substantially pure SNS-595 substance. wherein the substantially pure SNS-595 substance comprises about 0 to 0.02'% Compound **5**



5

at the time of production of the compositions based on total weight of the substantially pure SNS-595 substance.

[0015] In some examples, compositions are provided that comprise SNS-595 and water, wherein about 100 mg of SNS-595 is present for every 10 mL of the compositions, wherein the compositions are essentially free of visible particles, and wherein the compositions are stable at, for example, 3, 6, 9, 12, or 24 months after production.

[0016] In some examples, compositions are provided that comprise SNS-595 and water, wherein about 100 mg of SNS-595 is present for every 10 mL of the compositions, wherein the compositions are essentially free of sub-visible particles, and wherein the compositions are stable at, for example, 3, 6, 9, 12, or 24 months after production.

[0017] In some examples, the processes described herein are performed on a kilogram scale.

4. BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1 illustrates the observed relationship between amounts of Compound **6** in SNS-595 bulk drug product solutions formulated from drug substances having different amounts of Compound 4.

[0019] Figure *2* illustrates the observed relationship between the amount of Compound **4** in SNS-595 drug substance and the amount of residual Compound **1** in Compound **3** used to prepare the drug substance.

[0020] Figure 3 illustrates the observed relationship between the amount of Compound **5** in SNS-595 dmg substance and the amount of residual Compound **1** in Compound **3** used to prepare the drug substance.