CLAIMS

What is claimed is:

1. A solid composition comprising sincalide, wherein the composition does not contain a dibasic potassium phosphate buffer, and wherein the composition is stable in storage.

2. The solid composition of claim 1, wherein the composition does not contain any phosphate buffer.

3. The solid composition of claim 1, wherein the composition also does not contain polysorbate 20 and/or polysorbate 80.

4. The solid composition of claim 3, wherein the composition does not contain any surfactant/solubilizer.

5. The solid composition of claim 1, wherein the composition does not contain dibasic potassium phosphate and does not contain either or both polysorbate 20 and polysorbate 80.

6. The solid composition of claim 1, wherein the composition further comprises a stabilizer and/or a bulking agent/tonicity adjuster.

7. The solid composition of claim 6, wherein the stabilizer is selected from the group consisting of pentetic acid, arginine hydrochloride, L-methionine, L-lysine hydrochloride, sodium metabisulfite, and a combination thereof, and

wherein the bulking agent/tonicity adjuster comprises mannitol.

8. The solid composition of claim 1, wherein the composition maintains total impurities of less than 5% and/or a sincalide level of at least 90% after 15 months of storage at 25°C, 60% relative humidity when tested by a sincalide-specific assay.

9. The solid composition of claim 1, comprising:

(a) a therapeutically effective amount of sincalide,

(b) 1 to 4 mg pentetic acid,

(c) 15 to 45 mg arginine hydrochloride,

(d) 2 to 8 mg methionine,

(e) 7.5 to 30 mg lysine hydrochloride,

(f) 0.02 to 1 mg sodium metabisulfite,

(g) 85 to 340 mg mannitol, and

(e) a pH from 6.5 to 7.5 when reconstituted in a pharmaceutically acceptable diluent; and wherein the composition does not contain a buffer having a pKa within one unit of the pH, and wherein the composition is storage stable.

10. The solid composition of claim 1, wherein the composition is a lyophilized powder.

11. A method for the treatment, prevention, and/or diagnosis of gall bladder- and/or pancreatic disorders, or other diagnostic imaging of a patient in need thereof comprising administering a therapeutically or diagnostically effective amount of the composition of claim 1 in reconstituted form to the patient.

12. The method of claim 11, wherein the composition comprises:

(a) a chelator comprising pentetic acid,

(b) a stabilizer comprising a combination of L-arginine hydrochloride, L-methionine, L-lysine hydrochloride, and sodium metabisulfite,

(c) a bulking agent/tonicity adjuster comprising mannitol, and

wherein the composition further lacks dibasic potassium phosphate, and wherein the composition further lacks polysorbate 20.

13. A method of making a storage stable solid sincalide composition comprising:

(1) mixing:

(a) sincalide, and

(b) an excipient consisting essentially of (i) a stabilizer, (ii) a bulking agent/tonicity adjuster, (iii) a chelator, or (iv) any combination of (i), (ii) and (iii), and

(c) water

(2) adjusting the pH of the mixture to 6.5 to 7.5, and

(3) lyophilizing the pH-adjusted mixture,

wherein the storage stable sincalide composition does not contain a buffer having a pKa within one unit of the pH.

14. The method of claim 13, wherein the storage stable solid sincalide composition does not contain a surfactant/solubilizer.

15. A liquid composition comprising sincalide and a pharmaceutically acceptable carrier, wherein the composition is storage stable.

16. The liquid composition of claim 15, wherein the composition further comprises a stabilizer and/or a bulking agent/tonicity adjuster.

17. The liquid composition of claim 16, wherein the stabilizer is selected from the group consisting of pentetic acid, arginine hydrochloride, L-methionine, L-lysine hydrochloride, sodium metabisulfite, and a combination thereof, and

wherein the bulking agent/tonicity adjuster comprises mannitol.

18. The liquid composition of claim 15, wherein the composition lacks a phosphate buffer.

19. The liquid composition of claim 18, wherein the composition lacks any buffer.

20. The liquid composition of claim 15, wherein the composition does not contain polysorbate 20 and/or polysorbate 80.

21. The liquid composition of claim 20, wherein the composition does not contain any surfactant/solubilizer.

22. The liquid composition of claim 15, wherein the composition does not contain dibasic potassium phosphate and does not contain either or both polysorbate 20 and polysorbate 80.

23. The liquid composition of claim 15, wherein the composition maintains total impurities of less than 5% and/or a sincalide level of at least 90% after

i) 6 month of storage at 25°C, 65% relative humidity, or

ii) 12 months of storage at 2-8°C,

when tested by a sincalide-specific assay.

24. The liquid composition of claim 15, comprising:

(a) a therapeutically effective amount of sincalide,

(b) 1 to 4 mg pentetic acid,

(c) 15 to 45 mg arginine hydrochloride,

(d) 2 to 8 mg methionine,

(e) 7.5 to 30 mg lysine hydrochloride,

(f) 0.02 to 1 mg sodium metabisulfite, and

(g) 85 to 340 mg mannitol;

wherein the pH of the composition is 6.5 to 7.5, and

wherein the composition does not contain a buffer having a pKa within one unit of the pH, and wherein the composition is storage stable.

25. A method for the treatment, prevention, and/or diagnosis of gall bladder- and/or pancreatic disorders, or other diagnostic imaging of a patient in need thereof administering a therapeutically or diagnostically effective amount of the liquid composition of claim 15 to the patient.

26. The method of claim 25, further comprising diluting the composition prior to administering it.

27. The method of claim 26, wherein the liquid composition comprises:

(a) a therapeutically effective amount of sincalide,

(b) 1 to 4 mg pentetic acid,

(c) 15 to 45 mg arginine hydrochloride,

(d) 2 to 8 mg methionine,

(e) 7.5 to 30 mg lysine hydrochloride,

(f) 0.02 to 1 mg sodium metabisulfite,

(g) 85 to 340 mg mannitol, and

(e) a pH from 6.5 to 7.5.

28. The method of claim 27, wherein the composition does not contain a buffer having a pKa within one unit of the pH.

29. The method of claim 28, wherein the composition further does not contain a surfactant/solubilizer.

30. A method of making a storage stable liquid sincalide composition comprising:

(1) mixing:

(a) sincalide, and

(b) an excipient, wherein the excipient consists essentially of (i) a stabilizer, (ii) a bulking agent/tonicity adjuster, (iii) a chelator, or (iv) any combination of (i), (ii) and (iii), and

(c) water, and

(2) adjusting the pH of the mixture to 6.5 to 7.5,

wherein the storage stable sincalide composition maintains total impurities of less than 5%, and/or a sincalide level of at least 90% after

i) 6 month of storage at 25°C, 65% relative humidity, or

ii) 12 months of storage at 2-8°C,

when tested by a sincalide-specific assay.