What is claimed is

1. A pharmaceutical formulation comprising a crystalline hydrochloride monohydrate salt of (5S,8S)-8-[{(1R)-1-(3,5-Bis-trifluoromethyl)phenyl]-ethoxy}-methyl]-8-phenyl-1,7-diazaspiro[4.5]decan-2-one, lactose, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch, and magnesium stearate.

2. The formulation of claim 1 having the following PK profile

Dose (mg)	Cmax* (ng/mL)	Tmax**	AUC***	T1/2 (hours)
5	27.3	2	931	not calc.
10	52.7	2.5	1820	not calc
25	119	2.5	17200	183
50	276	3	33600	171
100	475	2	74400	181
200	944	4	148000	169

*Mean maximum plasma concentration following single administration.
** Median time of maximum plasma concentration from administration.
*** Integrated concentration over the period 0 to 72 hours post administration.

3. The formulation of either claim 1 or claim 2 wherein the hydrochloride monohydrate salt has an X-ray Powder Diffraction Pattern containing the following characteristic peaks expressed in terms of diffraction angle (in 2 θ, all values reflect an accuracy of ± 0.2): 16.1; 18.4; 21.6; 23.5.

4. A capsule containing an amount of the formulation of either of claims 1 or 2 providing a 2.5 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with

0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	69%	64% - 74%
15	88%	83% - 94%
30	94%	90% - 100%
45	97%	93% - 102%
60	98%	94% - 103%

5. A capsule containing an amount of the formulation of either of claims 1 or 2 providing a 10.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM.

Time (min.)	Average % of active initially present released	Range of % active
5	87%	82% - 91%
15	95%	91% - 98%
30	98%	94% - 100%
45	98%	95% - 101%
60	99%	96% - 100%

6. A capsule containing an amount of the formulation of either of claims 1 or 2 providing a 50.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released over n samples
5	88%	74% - 96%
15	97%	91% - 101%
30	99%	94% - 102%
45	100%	95% - 102%
60	100%	96% - 103%

7. A method of treating and/or preventing nausea and/or emesis in a mammal comprising administering to the mammal the formulation of either of claims 1 or 2.

8. A method of treating and/or preventing nausea and/or emesis in a mammal comprising administering to the mammal the formulation of claims 3.

9. The formulation of either of claims 1 to 2 wherein said lactose is lactose monohydrate.

10. A capsule filled with a granulate of Formula I which is characterized by having a Q-45 of not less than 75% when tested as a six tablet average under S-1 conditions.

11. A pharmaceutical formulation according to either of claims 1 or 2 prepared by the process comprising:

(a) preparing a granulate by the process comprising:

(i) dry blending crystalline hydrochloride monohydrate salt of Formula I, lactose monohydrate, croscarmellose sodium and pregelatinized starch to provide a homogeneous powder blend;

(ii) granulating the homogeneous powder blend provided in Step "a" with purified water until a granulate containing less than about 32 wt.% water is provided;

(iii) wet milling the granulate provided in step "b" through an 8 to 10 mesh screen sieve; and

(iv) drying the wet, milled granulate produced in Step "c" in a fluid bed dryer; and

(b) dry blending the granulate prepared in Step "a" with microcrystalline cellulose, croscarmellose sodium, and magnesium stearate to form a homogeneous powdered formulation.

12. A capsule containing an amount of the formulation of claim 11 providing a 2.5 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	69%	64% - 74%
15	88%	83% - 94%
30	94%	90% - 100%
45	97%	93% - 102%
60	98%	94% - 103%

13. A capsule containing an amount of the formulation of claim 11 providing a 10.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with

0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	87%	82% - 91%
15	95%	91% - 98%
30	98%	94% - 100%
45	98%	95% - 101%
60	99%	96% - 100%

14. A capsule containing an amount of the formulation of claim 11 providing a 50.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	88%	74% - 96%
15	97%	91% - 101%
30	99%	94% - 102%
45	100%	95% - 102%
60	100%	96% - 103%

15. A method of providing anti-emesis treatment and/or anti-nausea treatment to a mammal in need thereof comprising administering to the mammal the formulation of any of claims 10, and 12, to 15.

16. The formulation of claim 11 having the following PK profile when administered to a human.

Dose (mg)	Cmax* (ng/mL)	Tmax**	AUC***	T1/2 (hours)
5	27.3	2	931	not calc.
10	52.7	2.5	1820	not calc
25	119	2.5	17200	183
50	276	3	33600	171
100	475	2	74400	181
200	944	4	148000	169

*Mean maximum plasma concentration following single administration.
** Median time of maximum plasma concentration from administration.
*** Integrated concentration over the period 0 to 72 hours post administration

17. The formulation of claim 1 further comprising a chemotherapeutic agent.

18. The formulation of claim 17 wherein the chemotherapeutic agent is temozolomide.

19. A method of providing therapy for delayed onset emesis and/or delayed onset nausea along with chemotherapy by administering the formulation of either of claims 17 or 18 to a patient in need of chemotherapy.

20. The treatment method of claim 15 further comprising contemporaneous administration of a chemotherapeutic agent.

21. The treatment method of claim 20 wherein the chemotherapeutic agent is temozolomide.

22. A method of treating and/or preventing nausea and/or emesis in a mammal comprising administering to the mammal the formulation of claim 4.

23. A method of treating and/or preventing nausea and/or emesis in a mammal comprising administering to the mammal the formulation of claim 5.

24. A method of treating and/or preventing nausea and/or emesis in a mammal comprising administering to the mammal the formulation of claim 6.

25. The process of claim 11 wherein the crystalline hydrochloride monohydrate salt used in Step "a" has an X-ray powder diffraction spectrum containing the following characteristic peaks expressed in terms of diffraction angle (in 2 θ, all values reflect an accuracy of ± 0.2) lattice "d" spacing (in angstroms) and relative peak intensities("RI") shown in Table Ia; and

Table Ia

Diffraction angle (2θ ± 0.2)	RI	Lattice Spacing (Å ± 0.04)
16.1	Medium	5.49
18.4	Medium	4.83
21.6	Strong	4.11
23.5	Weak	3.78

What is claimed is:

1. A pharmaceutical formulation comprising a_crystalline hydrochloride monohydrate salt of (5S,8S)-8-[{(1R)-1-(3,5-Bis-(trifluoromethyl)phenyl]-ethoxy}-methyl]-8-phenyl-1, 7-diazaspiro[4.5]decan-2-one, lactose, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch, and magnesium stearate.

2. The formulation of claim 1 having the following PK profile

Dose (mg)	Cmax* (ng/mL)	Tmax**	AUC***	T½ (hours)
5	27.3	2	931	not calc.
10	52.7	2.5	1820	not calc
25	119	2.5	17200	183
50	276	3	33600	171
100	475	2	74400	181
200	944	4	148000	169

*Mean maximum plasma concentration following single administration.
**Median time of maximum plasma concentration from administration.
***Integrated concentration over the period 0 to 72 hours post administration.

3. The formulation of claim 1 wherein the hydrochloride monohydrate salt has an X-ray Powder Diffraction Pattern containing the following characteristic peaks expressed in terms of diffraction angle (in 2 0 θ, all values reflect an accuracy of ±0.2), lattice "d" spacing (in angstroms) and relative peak intensities("RI"):

Diffraction angle (2θ ± 0.2)	RI	Lattice Spacing (Å ± 0.04)
16.1	Medium	5.49
18.4	Medium	4.83
21.6	Strong	4.11
23.5	Weak	3.78.

4. The formulation of claim 2 wherein the hydrochloride monohydrate salt has an X-ray Powder Diffraction Pattern containing the following characteristic peaks expressed in terms of diffraction angle (in 2 θ, all values reflect an accuracy of ±0.2) lattice "d" spacing (in angstroms) and relative peak intensities("RI"):

Diffraction angle (2θ ± 0.2)	RI	Lattice Spacing (Å ± 0.04)
16.1	Medium	5.49
18.4	Medium	4.83
21.6	Strong	4.11
23.5	Weak	3.78.

5. A capsule containing an amount of the formulation of claim 1 providing a 2.5 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle

Time (min.)	Average % of active initially present released	Range of % active released
5	69%	64%-74%
15	88%	83%-94%
30	94%	90%-100%
45	97%	93%-102%
60	98%	94%-103%.

6. A capsule containing an amount of the formulation of claim 1 providing a 10.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	87%	82%-91%
15	95%	91%-98%
30	98%	94%-100%
45	98%	95%-101%
60	99%	96%-100%.

7. A capsule containing an amount of the formulation of claim 1 providing a 50.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	88%	74%-96%
15	97%	91%-101%
30	99%	94%-102%
45	100%	95%-102%
60	100%	96%-103%.

8. The formulation of claim 1 wherein said lactose is lactose monohydrate.

9. A capsule filled with a granulate prepared in accordance with claim 1 which is characterized by having a Q-45 of not less than 75% when tested as a six tablet average under S-1 conditions.

10. A pharmaceutical formulation according to claim 1 prepared by the process comprising:

(a) preparing a granulate by the process comprising:

(i) dry blending crystalline hydrochloride monohydrate salt of Formula I, lactose monohydrate, croscarmellose sodium and pregelatinized starch to provide a homogeneous powder blend;

(ii) granulating the homogeneous powder blend provided in Step "a" with purified water until a granulate containing less than about 32 wt.% water is provided;

(iii) wet milling the granulate provided in step "b" through an 8 to 10 mesh screen sieve; and

(iv)drying the wet, milled granulate produced in Step "c"in a fluid bed dryer; and

(b) blending the granulate prepared in Step "a" with microcrystalline cellulose, croscarmellose sodium, and magnesium stearate to form a homogeneous powdered formulation.

11. The formulation of claim 10, wherein the crystalline hydrochloride monohydrate salt used in Step "a" has an X-ray powder diffraction spectrum containing the following characteristic peaks expressed in terms of diffraction angle (in 2 θ, all values reflect an accuracy of ±0.2) of 16.1, 18.4, 21.6, and 23.5.

12. A capsule containing an amount of the formulation of claim **11** providing a 2.5 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	69%	64%-74%
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30	94%	90%-100%
45	97%	93%-102%
60	98%	94%-103%.

13. A capsule containing an amount of the formulation of claim 11 providing a 10.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
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15	95%	91%-98%
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45	98%	95%-101%
60	99%	96%-100%.

14. A capsule containing an amount of the formulation of claim 11 providing a 50.0 mg dose of the hydrochloride monohydrate which provides the following dissolution profile in 900 mL of dissolution medium comprising 0.25% sodium lauryl sulfate solution buffered with 0.05 M sodium acetate at pH 4.5 determined using a USP 2 Apparatus Paddle Stirrer with sinkers operated at 75 RPM

Time (min.)	Average % of active initially present released	Range of % active released
5	88%	74%-96%
15	97%	91%-101%
30	99%	94%-102%
45	100%	95%-102%
60	100%	96%-103%.

15. The formulation of claim 11 having the following PK profile

Dose (mg)	Cmax* (ng/mL)	Tmax**	AUC***	T½ (hours)
5	27.3	2	931	not calc.
10	52.7	2.5	1820	not calc
25	119	2.5	17200	183
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100	475	2	74400	181
200	944	4	148000	169

*Mean maximum plasma concentration following single administration.
**Median time of maximum plasma concentration from administration.
***Integrated concentration over the period 0 to 72 hours post administration.

16. The formulation of claim 1 further comprising a chemotherapeutic agent.

17. The formulation of claim 16 wherein the chemotherapeutic agent is temozolomide.

18. The combination of the formulation of claim 1 and other therapeutic agents.