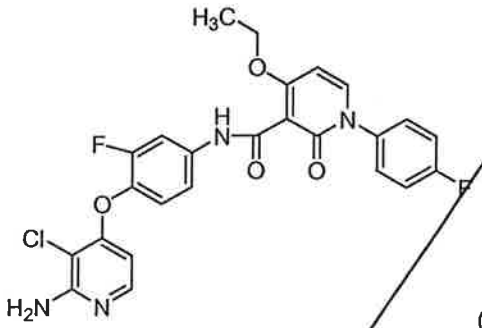
CLAIMS

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising (i) particles of Compound (I) in Form N-1



(I);

(ii) stabilizer; and (iii) at least one pharmaceutically acceptable carrier and/or diluent; wherein said particles have a diameter (D_{90}) in the range of from 1 to 50 microns and said stabilizer is disposed on said particles.

2. The pharmaceutical composition according to Claim 1, wherein said Form N-1 is characterized by one or more of the following:

a) a simulated powder x-ray diffraction pattern substantially as shown in Figure 1, and/or an observed powder x-ray diffraction pattern substantially as shown in Figure 1;

b) a powder x-ray diffraction pattern comprising four or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.2±0.2; 7.7±0.2; 11.0±0.2; 12.2±0.2; 18.5±0.2; 21.6±0.2; 22.2±0.2; and 23.0±0.2, wherein the PXRD pattern of Form N-1 is measured at a temperature of about 25 °C;

c) a powder x-ray diffraction pattern comprising five or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.2±0.2; 7.7±0.2; 11.0±0.2; 12.2±0.2; 18.5±0.2; 21.6±0.2; 22.2±0.2; and 23.0±0.2, wherein the PXRD pattern of Form N-1 is measured at a temperature of about 25 °C;

d) unit cell parameters substantially equal to the following:

Cell dimensions:

a = 14.45 Å

b = 19.21 Å

c = 8.89 Å

α = 90.0°

β = 95.7°

γ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form N-1 are measured at a temperature of about 25 °C;

e) unit cell parameters substantially equal to the following:

Cell dimensions:

a = 14.43 Å

b = 19.17 Å

c = 8.83 Å

α = 90.0°

β = 95.4°

γ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form N-1 are measured at a temperature of about -30 °C; and/or

f) a melting point in the range of from about 211 °C to about 217 °C.

3. The pharmaceutical composition according to Claim 1, wherein: said stabilizer is a cellulose ether polymer; said diluent is an aqueous medium; and said particles of Compound (I) in Form N-1 are dispersed in said aqueous medium.

4. The pharmaceutical composition according to Claim 3, further comprising:

a) from 0.1 to 5% (w/v) cellulose ether polymer selected from hydroxypropyl cellulose, hydroxypropyl methyl cellulose, and methyl cellulose;

b) from 0.1 to 5% (w/v) microcrystalline cellulose;

c) from 0.01 to 2% (w/v) sorbitan ester, sodium lauryl sulfate, dodecyl sulfate, and/or polyoxyethylene-polyoxypropylene-polyoxyethylene block copolymer;

d) from 1 to 40% (w/v) sweetener; and

e) from 48 to 98.7% (w/v) aqueous medium.

5. The pharmaceutical composition according to Claim 1, wherein said pharmaceutical composition is a solid oral dosage form comprising:

(i) from 10 to 40 weight % particles of Compound (I) in Form N-1;

(ii) from 2 to 11 weight % disintegrant;

(iii) from 1 to 7 weight % stabilizer;

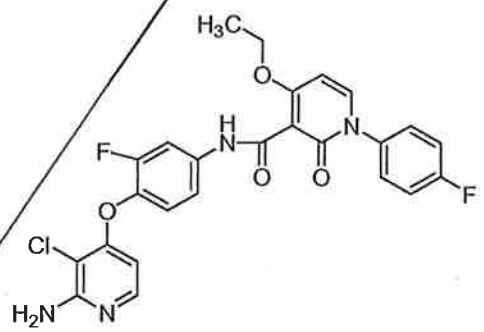
(iv) from 50 to 86 weight % filler;

(v) 0.1 to 1.1 weight % lubricant; and

(vi) from 0.1 to 0.7 weight % glidant, based on the total weight of the tablet.

6. The pharmaceutical composition according to Claim 5, wherein said stabilizer is a cellulose ether polymer selected from hydroxypropyl cellulose, hydroxypropyl methyl cellulose, and methyl cellulose;

7. Use of Compound (I)



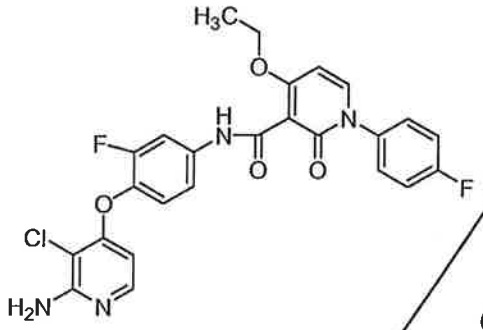
(I)

in the manufacture of a medicament for the treatment of cancer, wherein said Compound (I) is provided as particles of crystalline Form N-1 and said particles have a diameter (D_{90}) in the range of from 1 to 30 microns.

8. The use according to Claim 7, wherein said cancer is bladder cancer, breast cancer, colorectal cancer, gastric cancer, head and neck cancer, kidney cancer, liver

cancer, lung cancer, ovarian cancer, pancreas/gall bladder cancer, prostate cancer, thyroid cancer, osteosarcoma, rhabdomyosarcoma, melanoma, glioblastomas/astrocytomas, MFH/fibrosarcoma, or mesothelioma.

9. A crystalline form of Compound (I):



(I)

comprising sesquihydrate Form H1.5-2.

10. The crystalline form according to Claim 9, wherein said Form H1.5-2 is characterized by one or more of the following:

a) a simulated powder x-ray diffraction pattern substantially as shown in Figure 2;

b) a powder x-ray diffraction pattern comprising four or more 2θ values (CuKα λ=1.5418 Å) selected from: 7.4±0.2; 10.4±0.2; 12.2±0.2; 13.4±0.2; 18.9±0.2; 19.7±0.2; 21.5±0.2; and 22.0±0.2, wherein the PXRD pattern of Form H1.5-2 is measured at a temperature of about 25 °C; and/or

c) by unit cell parameters substantially equal to the following:

Cell dimensions:

a = 11.62 Å

b = 23.86 Å

c = 9.09 Å

α = 90.0°

β = 84.4°

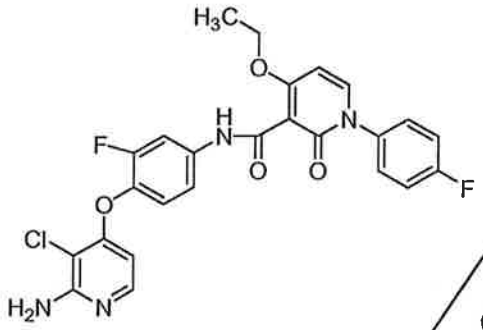
γ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form H1.5-2 are measured at a temperature of about -30 °C.

11. A crystalline form of Compound (I):



(I)

comprising the monohydrate, monohydrochloric acid salt Form H-1.

12. The crystalline form according to Claim 11, wherein said Form H-1 is characterized by one or more of the following:

a) a simulated powder x-ray diffraction pattern substantially as shown in Figure 3 and/or an observed powder x-ray diffraction pattern substantially as shown in Figure 3;

b) four or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.3±0.2, 7.0±0.2, 9.4±0.2, 15.5±0.2, 16.6±0.2, 18.7±0.2, 20.7±0.2, and 23.9±0.2, wherein the PXRD pattern of Form H-1 is measured at a temperature of about 25 °C;

c) unit cell parameters substantially equal to the following:

Cell dimensions:

a = 14.45 Å

b = 25.34 Å

c = 7.09 Å

α = 90.0°

β = 100.2°

γ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form H-1 are measured at a temperature of about 25 °C; and/or

d) unit cell parameters substantially equal to the following:

Cell dimensions:

a = 14.42 Å

b = 25.38 Å

c = 7.02 Å

α = 90.0°

β = 100.1°

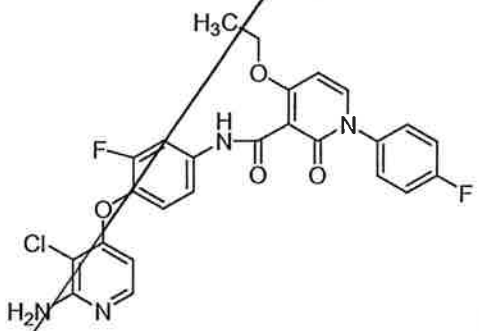
γ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form H-1 are measured at a temperature of about -50 °C.

13. A crystalline form of Compound (I):



(I)

comprising the phosphoric acid salt.

14. The crystalline form according to Claim 13 characterized by one or more of the following:

a) an observed powder x-ray diffraction pattern substantially as shown in Figure 5; and/or

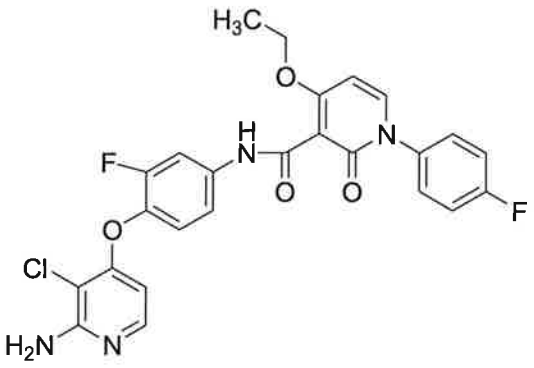
b) four or more 2θ values (CuKα λ=1.5418Å) selected from: 4.8±0.2, 6.1±0.2, 7.4±0.2, 9.2±0.2, 9.7±0.2, 11.3±0.2, 12.2±0.2, 13.3±0.2, 16.9±0.2, 22.5±0.2, and

23.5±0.2, wherein the PXRD pattern of the salt is measured at a temperature of about 25 °C.

CLAIMS

1. A pharmaceutical composition comprising

(i) particles of Compound (I) in Form N-1



(I);

(ii) stabilizer; and (iii) at least one pharmaceutically acceptable carrier and/or diluent; wherein said particles have a diameter (D_{90}) in the range of from 1 to 50 microns and said stabilizer is disposed on said particles;
wherein said stabilizer is a cellulose ether polymer;
wherein said Form N-1 is **characterized by** one or more of the following:

(a) a simulated powder x-ray diffraction (PXRD) pattern substantially as shown in Figure 1, and/or an observed PXRD pattern substantially as shown in Figure 1;

b) a PXRD pattern comprising four or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.2±0.2; 7.7±0.2; 11.0>±0.2; 12.2±0.2; 18.5±0.2; 21.6±0.2; 22.2±0.2; and 23.0±0.2, wherein the PXRD pattern of Form N-1 is measured at a temperature of about 25°C;

c) a PXRD pattern comprising five or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.2±0.2; 7.7±0.2; 11.0±0.2; 12.2±0.2; 18.5±0.2; 21.6±0.2; 22.2±0.2; and 23.0±0.2, wherein the PXRD pattern of Form N-1 is measured at a temperature of about 25°C;

d) unit cell parameters substantially equal to the following:

Cell dimensions:

a = 14.45 Å

b = 19.21 Å

c = 8.89 Å

α = 90.0°

β = 95.7°

λ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form N-1 are measured at a temperature of about 25°C;

e) unit cell parameters substantially equal to the following:

Cell dimensions:

a = 14.43 Å

b= 19.17 Å

c = 8.83 Å

α = 90.0°

β = 95.4°

λ = 90.0°

Space group: $P2_1/c$

Molecules of Compound (I)/asymmetric unit: 1

wherein the unit cell parameters of Form N-1 are measured at a temperature of about -30°C; and/or

f) a melting point in the range of from about 211°C to about 217°C.

2. The pharmaceutical composition according to Claim 1, wherein said Form N-1 is **characterized by** one or more of the following:

a) a simulated PXRD pattern substantially as shown in Figure 1, and/or an observed PXRD pattern substantially as shown in Figure 1;

b) a PXRD pattern comprising four or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.2±0.2; 7.7±0.2; 11.0±0.2; 12.2±0.2; 18.5±0.2; 21.6±0.2; 22.2±0.2; and 23.0±0.2, wherein the PXRD pattern of Form N-1 is measured at a temperature of about 25 °C; and/or

c) a PXRD pattern comprising five or more 2θ values (CuKα λ=1.5418 Å) selected from: 6.2±0.2; 7.7±0.2; 11.0±0.2; 12.2±0.2; 18.5±0.2; 21.6±0.2; 22.2±0.2; and 23.0±0.2, wherein the PXRD pattern of Form N-1 is measured at a temperature of about 25°C.

3. The pharmaceutical composition according to Claim 1, wherein said diluent is an aqueous medium; and said particles of Compound (I) in Form N-1 are dispersed in said aqueous medium.

4. The pharmaceutical composition according to Claim 3, further comprising:

a) from 0.1 to 5% (w/v) cellulose ether polymer selected from hydroxypropyl cellulose, hydroxypropyl methyl cellulose, and methyl cellulose;

b) from 0.1 to 5% (w/v) microcrystalline cellulose;

c) from 0.01 to 2% (w/v) sorbitan ester, sodium lauryl sulfate, dodecyl sulfate, and/or polyoxyethylene-polyoxypropylene-polyoxyethylene block copolymer;

d) from 1 to 40% (w/v) sweetener; and

e) from 48 to 98.7% (w/v) aqueous medium.

5. The pharmaceutical composition according to Claim 1, wherein said pharmaceutical composition is a solid oral dosage form comprising:

(i) from 10 to 40 weight % particles of Compound (I) in Form N-1;

(ii) from 2 to 11 weight % disintegrant;

(iii) from 1 to 7 weight % stabilizer;

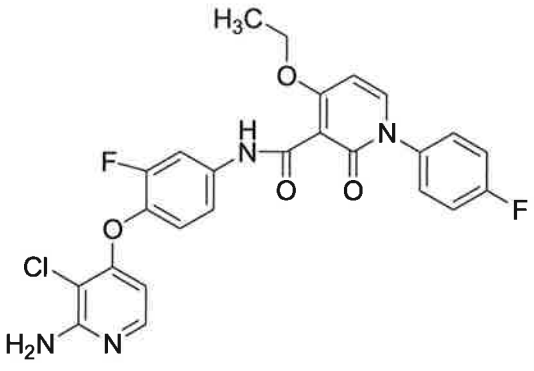
(iv) from 50 to 86 weight % filler;

(v) 0.1 to 1.1 weight % lubricant; and

(vi) from 0.1 to 0.7 weight % glidant, based on the total weight of the tablet.

6. The pharmaceutical composition according to Claim 5, wherein said stabilizer is a cellulose ether polymer selected from hydroxypropyl cellulose, hydroxypropyl methyl cellulose, and methyl cellulose.

7. Compound (I)



(I);

for use in the treatment of cancer, wherein said Compound (I) is provided as particles of crystalline Form N-1 as defined in Claim 1 and said particles have a diameter (D_{90}) in the range of from 1 to 30 microns.

8. The compound for use according to Claim 7, wherein said cancer is bladder cancer, breast cancer, colorectal cancer, gastric cancer, head and neck cancer, kidney cancer, liver cancer, lung cancer, ovarian cancer, pancreas/gall bladder cancer, prostate cancer, thyroid cancer, osteosarcoma, rhabdomyosarcoma, melanoma, glioblastomas/astrocytomas, MFH/fibrosarcoma, or mesothelioma.