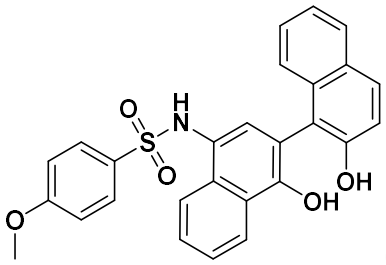
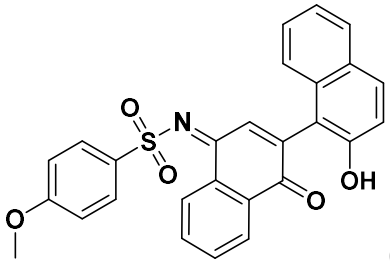
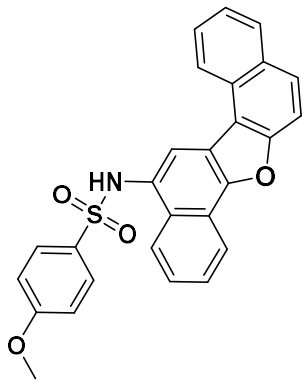
## CLAIMS

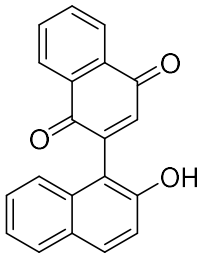
1. A composition, comprising a compound of formula (I):


(I),

wherein the composition is substantially free of an impurity selected from the group consisting of a compound of formula (II), a compound of formula (III), and a compound of formula (IV), or a combination thereof:


(II),


(III),

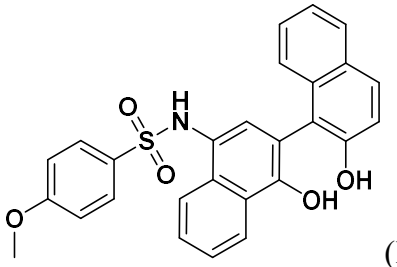

(IV).

2. The composition of claim 1, wherein the impurity is present in the composition at no more than about 2% area percentage by HPLC, at no more than about 1% area percentage by HPLC, at no more than about 0.5% area percentage by HPLC, at no more than about 0.1% area percentage by HPLC, or at no more than about 0.05% area percentage by HPLC.

3. The composition of claim 1, wherein the amount of the impurity is undetectable by HPLC.

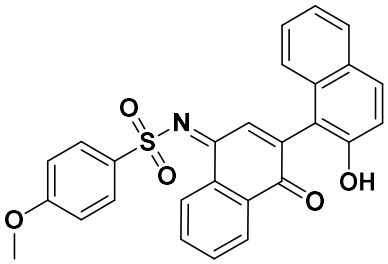
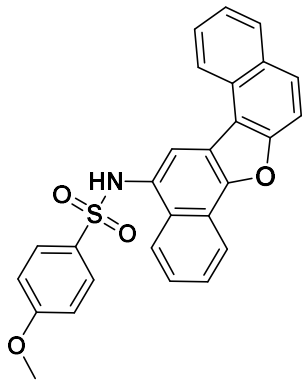
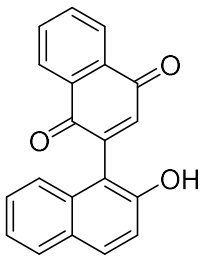
4. A composition, comprising:

(a) a compound of formula (I):


(I); and

(b) a pharmaceutically acceptable carrier,

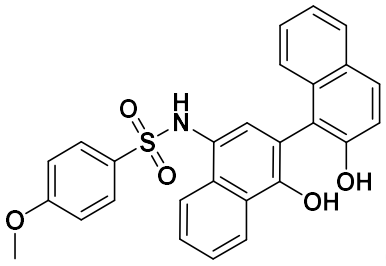
wherein the composition is substantially free of an impurity selected from the group consisting of a compound of formula (II), a compound of formula (III), and a compound of formula (IV), or a combination thereof:


(II),

(III),

(IV).

5. The composition of claim 4, wherein the impurity is present in the composition at no more than about 2% area percentage by HPLC, at no more than about 1% area percentage by HPLC, at no more than about 0.5% area percentage by HPLC, at no more than about 0.1% area percentage by HPLC, or at no more than about 0.05% area percentage by HPLC.

6. The composition of claim 5, wherein the amount of the impurity is undetectable by HPLC.

7. The composition of claim 1, comprising a compound of formula (I):

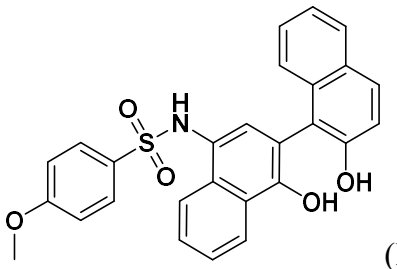

(I),

wherein the composition comprises no more than 2% of a compound of formula (II).

8. The composition of claim 7, wherein the composition comprises no more than 1% of a compound of formula (II) or no more than 0.2% of a compound of formula (II).

9. The composition of claim 4, comprising:

(a) a compound of formula (I):



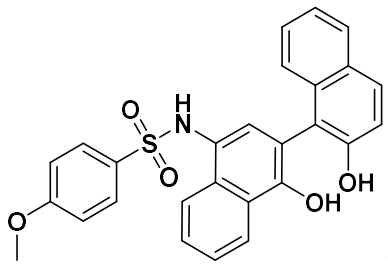

(I); and

(b) a pharmaceutically acceptable carrier,

wherein the composition comprises no more than 2% of a compound of formula (II).

10. The composition of claim 9, wherein the composition comprises no more than 1% of a compound of formula (II) or no more than 0.2% of a compound of formula (II).

11. The composition of claim 1, comprising a compound of formula (I):



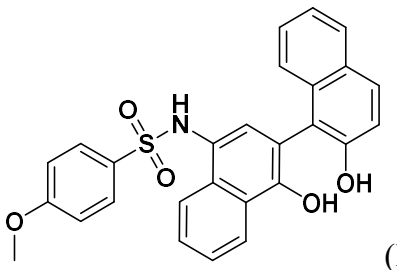

(I),

wherein the composition comprises no more than 0.05% of a compound of formula (III).

12. The composition of claim 11, wherein the composition comprises no more than 0.01% of a compound of formula (III).

13. The composition of claim 4, comprising:

(a) a compound of formula (I):



(I); and

(b) a pharmaceutically acceptable carrier,

wherein the composition comprises no more than 0.05% of a compound of formula (III).

14. The composition of claim 13, wherein the composition comprises no more than 0.01% of a compound of formula (III).

15. Use of a composition of any one of claims 1-14 in the manufacture of a medicament for treating cancer in an individual in need thereof.

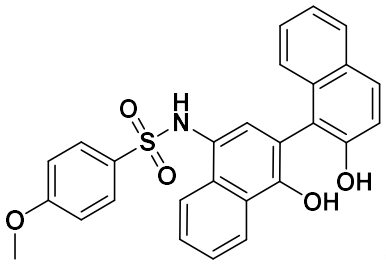
16. The use of clam 15, wherein the cancer is head and neck cancer, lung cancer, liver cancer, breast cancer, skin cancer, testicular cancer, colon cancer, rectal cancer, gastric cancer, bone cancer, spleen cancer, gall bladder cancer, stomach cancer, anal cancer, post-transplant lymphoproliferative disease, restenosis, ovarian cancer, colon cancer, multiple myeloma, prostate cancer, cervical cancer, brain cancer, pancreatic cancer, myelodysplastic syndrome, leukemia, lymphoma, neuroblastoma, kidney cancer, or metastatic melanoma.

17. Use of a composition of any one of claims 1-14 in the manufacture of a medicament for treating fibrosis in an individual in need thereof.

18. The use of claim 17, wherein the fibrosis is associated with pulmonary fibrosis, intestine fibrosis, pancreatic fibrosis, joint fibrosis, liver fibrosis, retroperitoneal fibrosis, myelofibrosis, renal fibrosis, bone marrow fibrosis, dermal fibrosis, non-alcoholic fatty liver disease, steatohepatitis, or systemic sclerosis.

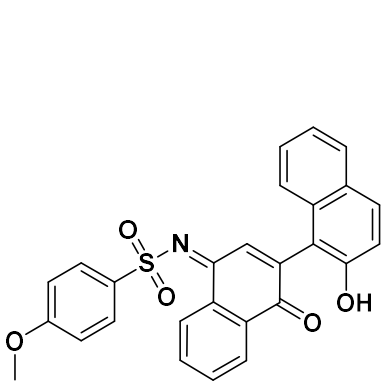
19. Use of a composition of any one of claims 1-14 in the manufacture of a medicament for treating an inflammatory disease or disorder, chemotherapy-induced peripheral neuropathy, diabetic neuropathy, familial amyloid polyneuropathy, cachexia, anaphylaxis, non-alcoholic fatty liver disease, or steatohepatitis in an individual in need thereof.

20. A method of evaluating the purity of a composition comprising a compound of formula (I):

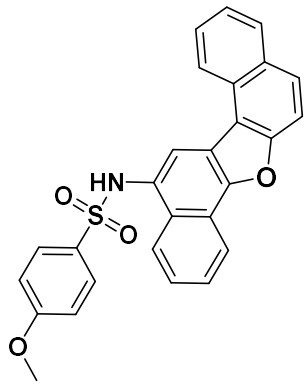


(I),

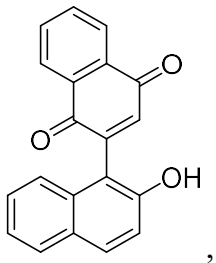
the method comprising assaying the composition for the presence of a compound selected from the group consisting of:



,



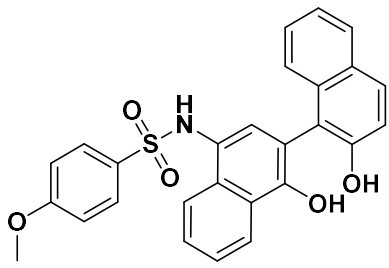
, and



,

optionally wherein the assaying comprises analysis using HPLC.

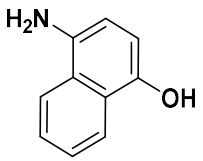
21. A process for preparing a compound of formula (I):



(I)

substantially free of an impurity, the process comprising:

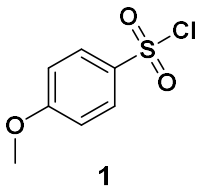
(a) contacting Compound 2:



**2**

,

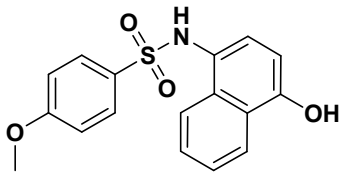
with Compound 1:



**1**

,

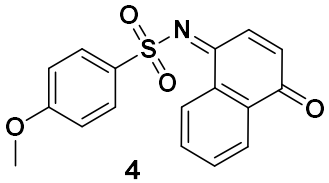
to produce Compound 3:



**3**

,

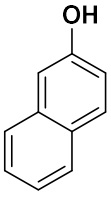
(b) contacting Compound 3 with an oxidizing agent to produce Compound 4:



**4**

,

(c) contacting Compound 4 with Compound 5:



**5**

,

in the presence of a coupling agent to produce the crude compound of formula (I);

(d) contacting the compound of formula (I) of step (c) with an alcohol, water, or a combination thereof, to form a mixture; and

(e) filtering the mixture of step (d) to isolate a precipitate, wherein the precipitate is the compound of formula (I) substantially free of an impurity.

22. The process of claim 21, further comprising after step (e) of claim 21:

(f) dissolving the precipitate in a first solvent to form a mixture and washing said mixture with a washing solution selected from brine, water, and a combination thereof; and

(g) separating the mixture of step (f) from the washing solution to obtain a separated mixture, and optionally

(h) concentrating the separated mixture of step (g) to form a concentrated mixture.

23. The process of claim 22, further comprising after step (h) of claim 22:

(i) contacting the concentrated mixture with a first solvent and adding charcoal to form a precipitate/charcoal mixture;

(j) filtering the precipitate/charcoal mixture to form a filtrate;

(k) adding a second solvent to the filtrate to form a second mixture comprising a second precipitate; and

(l) filtering the second mixture to retain the second precipitate.

24. The process of claim 21, further comprising after step (e) of claim 21:

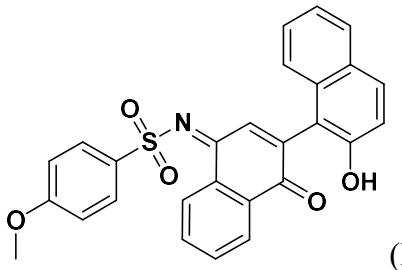
(f') dissolving the precipitate in a first solvent and adding charcoal to form a precipitate/charcoal mixture;

(g') filtering the precipitate/charcoal mixture to form a filtrate;

(h') adding a second solvent to the filtrate to form a second mixture comprising a second precipitate; and

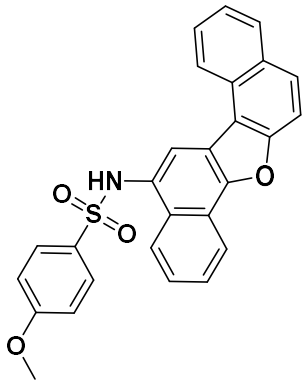
(i') filtering the second mixture to retain the second precipitate.

25. The process of claim 23 or 24, wherein the second precipitate is a compound of formula (I) substantially free of a compound of formula (II):




(II) or

a compound of formula (III):




(III).

26. A composition, comprising a compound of Formula (I) prepared according to any one of claims 21-25.

27. A composition of any one of claims 1-14 for use in therapy.