Yet another objective of the present invention solution is to optionally fill the formulation of the present invention into capsules or to be adsorbed onto the surface of any adsorbing material, followed by formulation into discrete dosage forms either as tablets or capsules.

SUMMARY~~STATEMENT OF INVENTION~~

Accordingly, the present ~~invention~~ disclosure provides a pharmaceutical oral formulation containing NRC-AN-019 including its pharmaceutically acceptable salts and its polymorphs such as Form I, Form II and Form III thereof and a process for its preparation to enhance the bioavailability so as to achieve effective therapy against Chronic Myeloid Leukemia and other tumors such as head and neck cancer, prostate cancer and the like.

In a first aspect of the present disclosure, there is provided a pharmaceutical composition for oral administration comprising:

(a) a therapeutically effective amount of (3,5-bis trifluoromethyl)-N- [4-methyl-3- (4-pyridin-3yl-pyrimidin-2yl amino) phenyl] benzamide (NRC-AN-019) or a pharmaceutically acceptable salt thereof;

(b) a lipophilic phase;

(c) at least one pharmaceutically acceptable surfactant; and

(d) a pharmaceutically acceptable water miscible solvent.

In a second aspect of the present disclosure, there is provided a pharmaceutical composition disclosed herein for use in the treatment of the human or animal body by therapy.

In a third aspect of the present disclosure, there is provided a pharmaceutical composition for use as disclosed herein, which is for use in the treatment of cancer,

In a fourth aspect of the present disclosure, there is provided a process for producing a pharmaceutical composition disclosed herein, which process comprises

- mixing NRC-AN-019 with a water miscible solvent,
- addition of a lipophilic phase,
- addition of a surfactant and optionally a co-surfactant, and
- stirring with the application of heat.

The present ~~invention~~ disclosure also provides a method of treating cancer which method comprises administering to a patient in need thereof the pharmaceutical composition of the present ~~invention~~disclosure.

The present ~~invention~~ disclosure also provides a pharmaceutical composition for use in the treatment of the human or animal body.

The present ~~invention~~ disclosure also provides the use of the formulation of the present ~~invention~~ disclosure in the manufacture of a medicament for the treatment of cancer.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a pharmaceutical composition in the form of self emulsifying system which is capable of forming an *in- situ* emulsion after oral administration when it comes in contact with the gastric fluid, comprising NRC-AN-019 as an active ingredient useful for the treatment of CML and other tumors such as head and neck cancer, prostate cancer and the like.

based flavors, either individually or in combination, wherein the flavoring agent is preferably present in an amount from 0.1 wt% to about 10 wt% relative to the total weight of the composition, more preferably from 0.25 wt% to 1 wt% relative to the total weight of the composition.

18. A pharmaceutical composition according to any preceding claim which is in the form of a solution, a soft gel, or a hard shell capsular formulation.

19. A pharmaceutical composition according to ~~as defined in~~ any preceding claim for use in ~~a method of~~ the treatment of the human or animal body by therapy.

20. ~~Use of a~~A pharmaceutical composition for use according to ~~as defined in any one of~~ claim~~s~~ 17~~1 to 18~~, which is ~~in the manufacture of a medicament~~ for use in the treatment of cancer.

21. A process for producing a pharmaceutical composition according to ~~as defined in~~ any one of claims 1 to 17, which process comprises
    - mixing NRC-AN-019 with a water miscible solvent,
    - addition of a lipophilic phase,
    - addition of a surfactant and optionally a co-surfactant, and
    - stirring with the application of heat.