Claims

[Claim 1] An oral solid formulation comprising:

irinotecan or a pharmaceutically acceptable salt thereof; and

an acidifying agent, wherein the acidifying agent is selected from the group consisting of acetic acid, citric acid, lactic acid, and any combinations thereof, and wherein the amount of the acidifying agent is from about 0.2 parts to about 10 parts by weight based on 1 part by weight of the irinotecan or pharmaceutically acceptable salt thereof.

[Claim 2] The oral solid formulation of claim 1, wherein, when a dissolution test takes place using the paddle method in the U.S. Pharmacopoeia (USP) with 900 mL of purified water, the dissolution medium of the oral solid formulation has a pH of about 1 to 5 in 30 minutes of the dissolution test.

[Claim 3] The oral solid formulation of claim 1 or 2, wherein the oral solid formulation is in the form of granules, a capsule, or a tablet.

[Claim 4] The oral solid formulation of any one of claims 1 to 3, wherein the oral solid formulation further comprises a pharmaceutically acceptable additive selected from the group consisting of a diluent, a binder, a disintegrant, a lubricant, and any combinations thereof.

[Claim 5] The oral solid formulation of claim 4, wherein the oral solid formulation comprises about 20wt% to about 80wt% of the diluent, about 1wt% to about 10wt% of the binder, about 2wt% to about 7wt% of the disintegrant, or about 0.5wt% to about 5wt% of the lubricant based on a total weight of the oral solid formulation.

[Claim 6] The oral solid formulation of any one of claims 1 to 5, wherein, when a dissolution test takes place using the paddle method in the U.S. Pharmacopoeia (USP) with 900 mL of purified water, a dissolution rate of an active ingredient in the solid formulation is about 80% or greater in 30 minutes of the dissolution test.

[Claim 7] Use of the oral solid formulation of any one of claims 1 to 6, in the manufacture of a medicament for treating cancer.

[Claim 8] A method of preparing an oral solid formulation according to any one of claims 1 to 6, the method comprising:

forming granules comprising irinotecan or a pharmaceutically acceptable salt thereof, a diluent, and a binder;

mixing the granules with a disintegrant and a lubricant to obtain a mixture; and

optionally, formulating the resultant mixture,

wherein, in the step of forming granules and/or mixing the granules, an acidifying agent is added,

wherein the acidifying agent is selected from the group consisting of acetic acid, citric acid, lactic acid, and any combinations thereof.

[Claim 9] The method of claim 8, wherein the step of forming granules is performed by wet granulation or dry granulation.

[Claim 10] The method of claim 9, wherein the wet granulation comprises forming granules by granulating a mixture of the irinotecan or pharmaceutically acceptable salt thereof and the diluent in combination with a binding solution including the binder, wherein the acidifying agent is added to the mixture and/or the binding solution.