What is claimed is:

1. A pharmaceutical composition comprising regorafenib, a hydrate, solvate, metabolite or pharmaceutically acceptable salt of regorafenib, or a polymorph thereof and at least one pharmaceutically acceptable excipient wherein the pharmaceutical composition is coated by a coating comprising a polyvinyl alcohol based polymer and optionally one or more further pharmaceutically acceptable excipients.

2. The composition of any of claim 1 which is a tablet.

3. The composition of any of claims 1 to 2 is an immediate release tablet.

4. The composition of any of claims 1 to 3 wherein the polyvinyl alcohol based polymer is a hydrolysed polyvinyl alcohol polymer, a partially hydrolysed polyvinyl alcohol polymer, an esterified polyvinyl alcohol polymer, a co-polymer thereof with polyethylene glycol or a mixture of the thereof.

5. The composition of claim 4 wherein the polyvinyl alcohol based polymer is a partially hydrolysed polyvinyl alcohol polymer.

6. The composition of any of claims 1 to 5 wherein the polyvinyl alcohol based polymer is present in an amount of 30 to 70% by weight of the total coating.

7. The composition of any of claims 1 to 6 wherein the coating comprises polyethylene glycol, propylene glycol, sorbitol, glycerol, maltitol, xylitol, mannitol, erythritol, glycerol trioleate, tributyl citrate, triethyl citrate acetyl triethyl citrate, glyceryl triacetate, stearic acid, medium chain triglycerides or a mixture thereof as plasticizer.

8. The composition of claim 7 wherein the plasticizer is polyethylene glycol.

9. The composition of any of claims 7 or 8 wherein the plasticizer is in an amount of 5 to 30% by weight of the total coating.

10. The composition of any of claims 1 to 9 comprising a solid dispersion comprising regorafenib.

11. The composition of claim 10 comprising regorafenib in an amorphous state and a pharmaceutically acceptable matrix wherein the matrix comprises polyvinylpyrrolidone, vinylpyrrolidone/vinylacetate copolymer, polyalkylene glycol, hydroxyalkyl, hydroxyalkyl methyl cellulose, carboxymethyl cellulose, sodium carboxymethyl cellulose, ethyl cellulose, polymethacrylates, polyvinyl alcohol, polyvinyl acetate, vinyl alcohol/vinyl acetate

copolymer, polyglycolized glycerides, xanthan gum, carrageenan, chitosan, chitin, polydextrin, dextrin, starch, proteins, sucrose, lactose, fructose, maltose, raffinose, sorbitol, lactitol, mannitol, maltitol, erythritol, inositol, trehalose, isomalt, inulin, maltodextrin, ß-cyclodextrin, hydroxypropyl-ß-cyclodextrin or sulfobutyl ether cyclodextrin or a mixture thereof.

12. The composition of any of claims 10 to 11 comprising regorafenib and the matrix agent in a weight ratio of 1:0.5 to 1:20.

13. The composition of any of claims 10 to 12 comprising regorafenib and polyvinylpyrrolidone, croscarmellose sodium and/or microcrystalline cellulose.

14. The composition of claim 13 comprising regorafenib and the sum of croscarmellose sodium and/or microcrystalline cellulose in a weight ratio of 1:0.5 to 1:20.

15. Film-coated pharmaceutical composition comprising regorafenib wherein the amount of 4-(4-amino-3-fluorophenoxy)pyridine-2-carboxylic acid methylamide is equal or less than 0.100 % by weight based on the amount of regorafenib.

16. Container containing molecular sieve and a pharmaceutical composition comprising regorafenib.

17. Pharmaceutical composition comprising regorafenib, a hydrate, solvate, metabolite or pharmaceutically acceptable salt of regorafenib, or a polymorph thereof, preferably regorafenib, wherein the pharmaceutical composition is coated by a coating wherein the coating is obtainable by a coating process wherein the outlet air temperature in the coating process is equal to or below 42 °C.

18. Process for the manufacture of a film-coated pharmaceutical composition comprising regorafenib wherein the coating liquid is sprayed onto the pharmaceutical composition in a pan or perforated drum coater and the outlet air temperature during the coating is equal to or below 42 °C.

CLAIMS

1. A pharmaceutical composition comprising regorafenib, a hydrate, solvate, metabolite or pharmaceutically acceptable salt of regorafenib, or a polymorph thereof and at least one pharmaceutically acceptable excipient wherein the pharmaceutical composition is coated by a coating comprising a polyvinyl alcohol based polymer and optionally one or more further pharmaceutically acceptable excipients wherein said metabolite is selected from the group consisting of 4-[4-({[4-chloro-3-(trifluoromethyl)phenyl]carbamoyl}amino)-3-fluorophenoxy]-N-methylpyridine-2-carboxamide 1-oxide, 4-[4-({[4-chloro-3-(trifluoromethyl)phenyl]carbamoyl}amino)-3-fluorophenoxy]-N-(hydroxymethyl)pyridine-2-carboxamide, 4-[4-({[4-chloro-3-(trifluoromethyl)phenyl]carbamoyl}amino)-3-fluorophenoxy]pyridine-2-carboxamide and 4-[4-({[4-chloro-3-(trifluoromethyl)phenyl]carbamoyl}amino)-3-fluorophenoxy]pyridine-2-carboxamide 1-oxide.

2. The composition of claim 1 comprising regorafenib as active ingredient.

3. The composition of any of claims 1 or 2 which is a tablet.

4. The composition of any of claims 1 to 3 is an immediate release tablet.

5. The composition of any of claims 1 to 4 wherein the polyvinyl alcohol based polymer is a hydrolysed polyvinyl alcohol polymer, a partially hydrolysed polyvinyl alcohol polymer, an esterified polyvinyl alcohol polymer, a co-polymer thereof with polyethylene glycol or a mixture of the thereof.

6. The composition of claim 5 wherein the polyvinyl alcohol based polymer is a partially hydrolysed polyvinyl alcohol polymer.

7. The composition of any of claims 1 to 6 wherein the polyvinyl alcohol based polymer is present in an amount of 30 to 70% by weight of the total coating.

8. The composition of any of claims 1 to 7 wherein the coating comprises polyethylene glycol, propylene glycol, sorbitol, glycerol, maltitol, xylitol, mannitol, erythritol, glycerol trioleate, tributyl citrate, triethyl citrate acetyl triethyl citrate, glyceryl triacetate, stearic acid, medium chain triglycerides or a mixture thereof as plasticizer.

9. The composition of claim 8 wherein the plasticizer is polyethylene glycol.

10. The composition of any of claims 8 or 9 wherein the plasticizer is in an amount of 5 to 30% by weight of the total coating.

11. The composition of any of claims 1 to 10 comprising a solid dispersion comprising regorafenib.

12. The composition of claim 11 comprising regorafenib in an amorphous state and a pharmaceutically acceptable matrix wherein the matrix comprises polyvinylpyrrolidone, vinylpyrrolidone/vinylacetate copolymer, polyalkylene glycol, hydroxyalkyl, hydroxyalkyl methyl cellulose, carboxymethyl cellulose, sodium carboxymethyl cellulose, ethyl cellulose, polymethacrylates, polyvinyl alcohol, polyvinyl acetate, vinyl alcohol/vinyl acetate copolymer, polyglycolized glycerides, xanthan gum, carrageenan, chitosan, chitin, polydextrin, dextrin, starch, proteins, sucrose, lactose, fructose, maltose, raffinose, sorbitol, lactitol, mannitol, maltitol, erythritol, inositol, trehalose, isomalt, inulin, maltodextrin, ß-cyclodextrin, hydroxypropyl-ß-cyclodextrin or sulfobutyl ether cyclodextrin or a mixture thereof.

13. The composition of any of claims 11 to 12 comprising regorafenib and the matrix agent in a weight ratio of 1:0.5 to 1:20.

14. The composition of any of claims 11 to 13 comprising regorafenib and polyvinylpyrrolidone, croscarmellose sodium and/or microcrystalline cellulose.

15. The composition of claim 14 comprising regorafenib and the sum of croscarmellose sodium and/or microcrystalline cellulose in a weight ratio of 1:0.5 to 1:20.