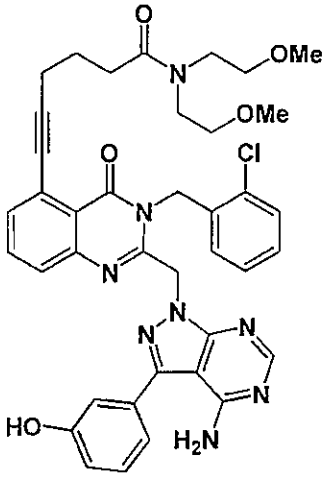
Claims

1. A method of increasing the stability to chemical degradation of a pharmaceutical formulation containing a compound of formula (I)

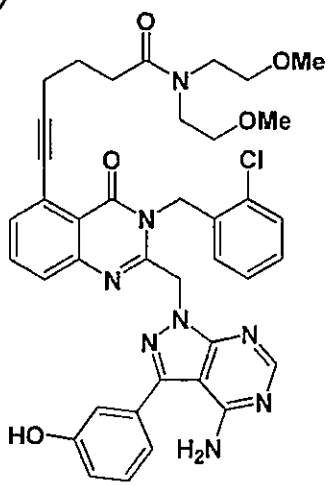


(I)

that is 6-(2-((4-amino-3-(3-hydroxyphenyl)-1*H*-pyrazolo[3,4-d]pyrimidin-1-yl) methyl)-3-(2-chlorobenzyl)-4-oxo-3,4-dihydroquinazolin-5-yl)-*N*,*N*-bis(2-methoxyethyl)hex-5-ynamide or a pharmaceutically acceptable salt thereof including all stereoisomers, tautomers and isotopic derivatives thereof and solvates thereof in particulate form as active ingredient

and particulate lactose which comprises including in said formulation a stabilizing amount of a particulate stabilizing agent selected from metal salts of stearic acid such as magnesium stearate and metal salts of stearyl fumarate.

2. Use of a particulate stabilizing agent selected from metal salts of stearic acid and metal salts of stearyl fumarate in a pharmaceutical formulation containing a compound of formula (I)



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ynamide or a pharmaceutically acceptable salt thereof including all stereoisomers, tautomers and isotopic derivatives thereof and solvates thereof in particulate form as active ingredient
and particulate lactose to increase the stability of the compound of formula (I) to *chemical degradation*.

3. A method according to claim 1 wherein the compound of formula (I) is in its free base form.

4. A method according to claim 3 wherein the compound of formula (I) is in solid crystalline anhydrous form.

5. A method according to claim 3 wherein the compound of formula (I) is in solid crystalline form having the X-ray powder diffraction pattern containing one, two, three or four peaks selected from (± 0.2) 17.6, 18.4, 22.5 and 24.2 degrees 2-theta.

6. A method according to any one of claims 1 and 3 to 5 wherein the stabilizing agent is a metal salt of stearic acid.

7. A method according to claim 6 wherein the stabilizing agent is magnesium stearate.

8. A method according to any one of claims 1 and 3 to 7 wherein the active ingredient has been micronized.

9. A method according to any one of claims 1 and 3 to 8 wherein the lactose is *α*-lactose monohydrate.

10. Use according to claim 2 wherein the compound of formula (I) is in its free base form.

11. Use according to claim 10 wherein the compound of formula (I) is in solid crystalline anhydrous form.

12. Use according to claim 10 wherein the compound of formula (I) is in solid crystalline form having a X-ray powder diffraction pattern containing one, two, three or four peaks selected from (± 0.2) 17.6, 18.4, 22.5 and 24.2 degrees 2-theta.

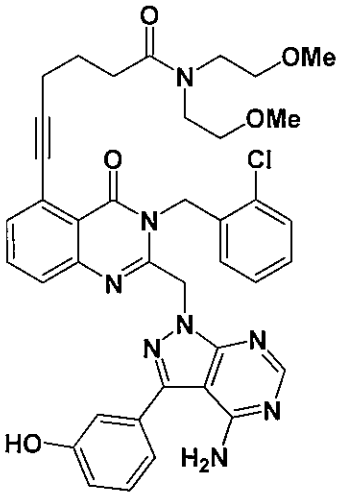
13. Use according to any one of claims 2 and 10 to 12 wherein the stabilizing agent is a metal salt of stearic acid.

14. Use according to claim 13 wherein the stabilizing agent is magnesium stearate.

15. Use according to claim 2 and 10 to 14 wherein the lactose is α-lactose monohydrate.

Claims

1. A method of increasing the stability to chemical degradation of a dry powder pharmaceutical formulation containing a compound of formula (I)



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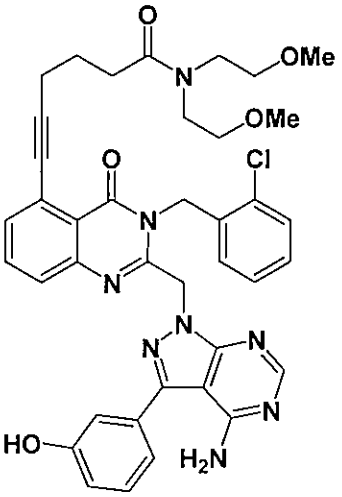
adding to said formulation a stabilizing amount of a particulate stabilizing agent selected from metal salts of stearic acid such as magnesium stearate and metal salts of stearyl fumarate wherein the particulate stabilizing agent acts as a protecting agent against chemical degradation of the alkyne group in the compound of formula (I).

2. Use of a particulate stabilizing agent selected from metal salts of stearic acid and metal salts of stearyl fumarate in a dry powder pharmaceutical formulation containing a compound of formula (I)



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3. A method according to claim 1 wherein the compound of formula (**I**) is in its free base form.

4. A method according to claim 3 wherein the compound of formula (**I**) is in solid crystalline anhydrous form.

5. A method according to claim 3 wherein the compound of formula (**I**) is in solid crystalline form having the X-ray powder diffraction pattern containing one, two, three or four peaks selected from (± 0.2) 17.6, 18.4, 22.5 and 24.2 degrees 2-theta.

6. A method according to any one of claims 1 and 3 to 5 wherein the stabilizing agent is a metal salt of stearic acid.

7. A method according to claim 6 wherein the stabilizing agent is magnesium stearate.

8. A method according to any one of claims 1 and 3 to 7 wherein the active ingredient has been micronized.

9. A method according to any one of claims 1 and 3 to 8 wherein the lactose is α-lactose monohydrate.

10. Use according to claim 2 wherein the compound of formula (**I**) is in its free base form.

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