

designated as Form I, which process comprises the following steps:

- (a) taking *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide in a mixture of ethanol and *n*-pentane;
- 5 (b) adding ethanolic solution of potassium tertiary butoxide or potassium ethoxide to the solution or suspension of step (a) or adding the solution or suspension of step (a) to ethanolic solution of potassium tertiary butoxide or potassium ethoxide; and
- (c) isolating the desired potassium salt.

10 In another embodiment the present disclosure relates to crystalline form of potassium salt of compound of formula (II) which is designated as Form II.

In another aspect, there is provided a process for the preparation of crystalline potassium salt of *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form II, which process comprises the following steps:

- (a) taking *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide in a mixture of tertiary butanol and *n*-pentane;
- (b) adding potassium tertiary butoxide in tertiary butanol to the solution or suspension of step (a) or adding the solution or suspension of step (a) to potassium tertiary butoxide in tertiary butanol; and
- 20 (c) isolating the desired potassium salt.

~~In another aspect, there is provided crystalline *N*-{4-[2,4 difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Y characterised by the X-ray Powder Diffraction (XRPD) pattern as provided in Fig. 14.~~

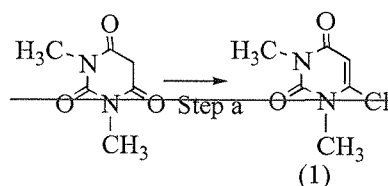
~~In another aspect, there is provided crystalline *N*-{4-[2,4 difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Y characterised by the Fourier Transform Infrared Spectroscopy (FT-IR) pattern wherein the ratio between the intensity of the absorption bands at wavelengths 1500 cm^{-1} and 1480 cm^{-1} is from 1:1.7 to 1:2.4.~~

In another aspect, there is provided crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Z characterised by the X-ray Powder Diffraction (XRPD) pattern as provided in Fig. 16.

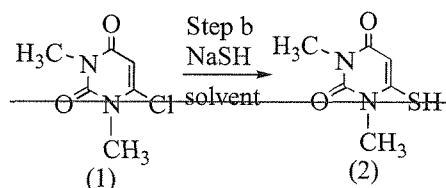
In another aspect, there is provided crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Z characterised by the Fourier Transform Infrared (FT-IR) Spectroscopy pattern wherein the ratio between the intensity of the absorption bands at wavelengths 1500 cm^{-1} and 1480 cm^{-1} is from 1:2.5 to 1:2.9.

In another aspect, there is provided a process for the preparation of *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide or pharmaceutically acceptable salt thereof, which process comprises the steps of

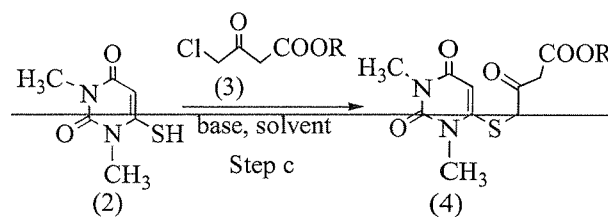
- (a) treating dimethylbarbituric acid with a suitable chlorinating agent to afford 6-chloro-1,3-dimethyluracil of formula (1);



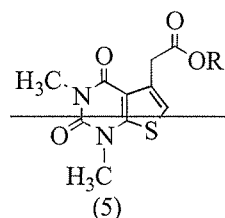
- (b) treating 6-chloro-1,3-dimethyluracil of formula (1) with sodium hydrosulphide hydrate to give 6-mercapto-1,3-dimethyluracil of the formula (2);



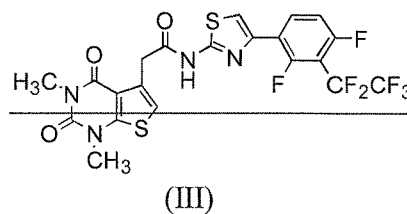
- (c) treating 6-mercapto-1,3-dimethyluracil of the formula (2) with the compound of formula (3) wherein R is (C₁-C₄)alkyl, to give ester compound of formula (4); and



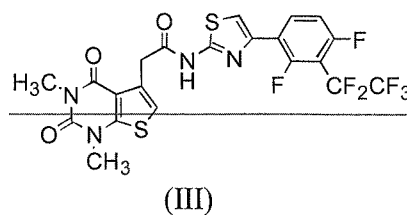
(d) ~~cyclising keto ester of the formula (4) to obtain thieno-pyrimidinyl ester of the formula (5)~~



5 In another aspect, there is provided ~~*N* {4 [2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide~~ having less than about 0.1% (by HPLC) of the compound of formula (III):



10 In another aspect, there is provided a compound of Formula (III)



or a pharmaceutically acceptable salt thereof.

- (a) taking *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide in a mixture of tertiary butanol and *n*-pentane;
- (b) adding potassium tertiary butoxide in tertiary butanol to the solution or suspension of step (a) or adding the solution or suspension of step (a) to potassium tertiary butoxide in tertiary butanol; and
- (c) isolating the desired potassium salt.

~~16. Crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Y characterised by the X-ray Powder Diffraction (XRPD) pattern as provided in Fig. 14.~~

~~17. The crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Y according to claim 16, characterised by the X-ray Powder Diffraction (XRPD) pattern comprising one or more of the following peaks expressed in terms of 2θ: 4.72, 9.40, 21.04, 25.87 and 31.73 ± 0.2.~~

~~18. Crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Y characterised by the Fourier Transform Infrared Spectroscopy (FT-IR) pattern wherein the ratio between the intensity of the absorption bands at wavelengths 1500 cm⁻¹ and 1480 cm⁻¹ is from 1:1.7 to 1:2.4.~~

~~19. Crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Z characterised by the X-ray Powder Diffraction (XRPD) pattern as provided in Fig. 16.~~

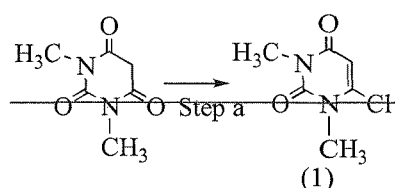
~~20. The crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Z according to claim 19, characterised by the X-ray Powder Diffraction (XRPD) pattern comprising one or more of the following peaks expressed in terms of 2θ: 10.63, 19.25, 22.11, 22.76 and 27.27 ± 0.2.~~

~~21. Crystalline *N*-{4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl}-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide designated as Form Z characterised by the Fourier Transform Infrared (FT-IR)~~

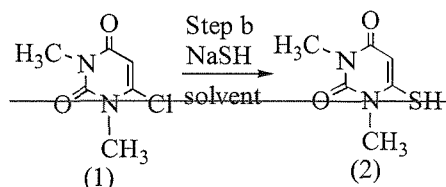
Spectroscopy pattern wherein the ratio between the intensity of the absorption bands at wavelengths 1500 cm^{-1} and 1480 cm^{-1} is from 1:2.5 to 1:2.9.

22. A process for the preparation of *N*-(4-[2,4-difluoro-3-(trifluoromethyl)phenyl]-1,3-thiazol-2-yl)-2-(1,3-dimethyl-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-*d*]pyrimidin-5-yl)acetamide or pharmaceutically acceptable salt thereof, which process comprises the steps of

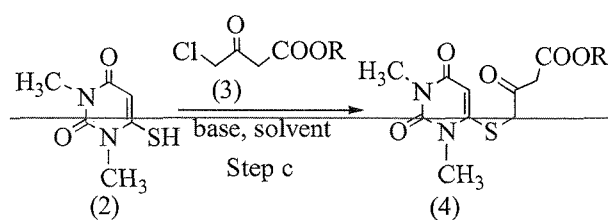
(a) treating dimethylbarbituric acid with a suitable chlorinating agent to afford 6-chloro-1,3-dimethyluracil of formula (1);



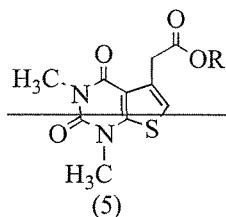
(b) treating 6-chloro-1,3-dimethyluracil of formula (1) with sodium hydrosulphide hydrate to give 6-mercapto-1,3-dimethyluracil of the formula (2);



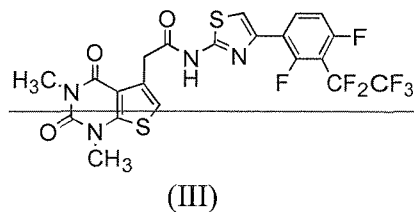
(c) treating 6-mercapto-1,3-dimethyluracil of the formula (2) with the compound of formula (3) wherein R is (C₁-C₄)alkyl, to give ester compound of formula (4); and



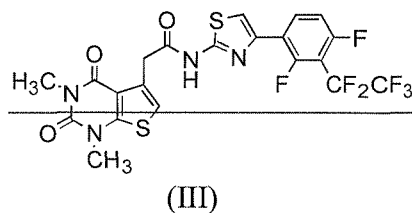
(d) cyclising keto-ester of the formula (4) to obtain thieno-pyrimidinyl ester of the formula (5)



23. ~~*N* {4 [2,4 difluoro 3 (trifluoromethyl)phenyl] 1,3 thiazol 2 yl} 2 (1,3 dimethyl 2,4 dioxo 1,2,3,4 tetrahydrothieno[2,3 *c*]pyrimidin 5 yl)acetamide having less than about 0.1 % (by HPLC) of the compound of formula (III):~~



- 5 24. ~~A compound of Formula (III)~~



~~or a pharmaceutically acceptable salt thereof.~~