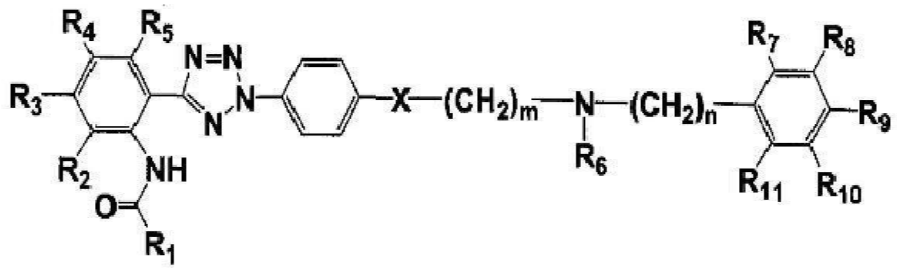
Claims

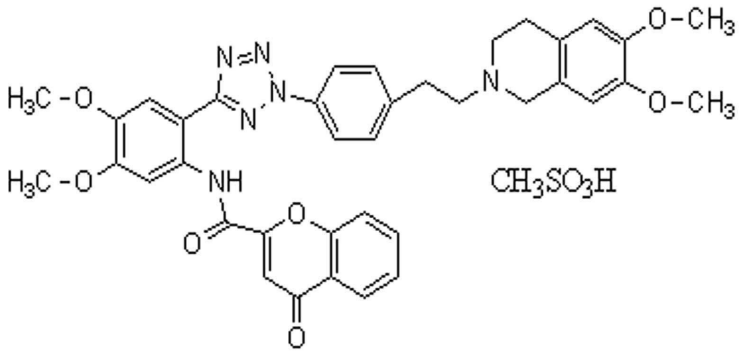
1. An amorphous solid dispersion comprising a tetrazole derivative of the formula (I) or a pharmaceutically acceptable salt thereof as an active ingredient:



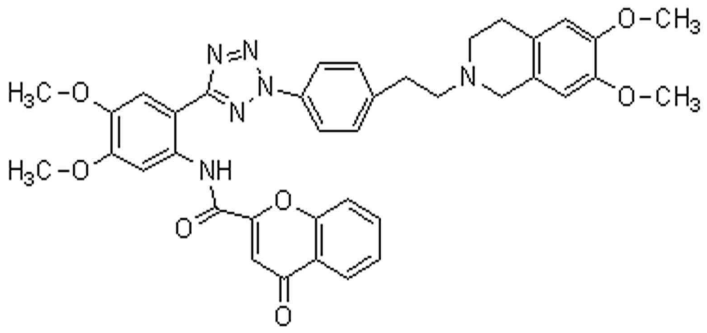
(I)

wherein,
R_1 is quinoline, isoquinoline, quinoxaline, pyridine, pyrazine, naphthalene, phenyl, thiophene, furan, 4-oxo-4H-chromene or cinnoline, which is unsubstituted or substituted by C_1-C_5alkyl, hydroxyl, C_1-$_5$alkoxy, halogen, trifluoromethyl, nitro or amino;
R_2 to R_5 and R_8 to R_{11} are each independently H, hydroxyl, halogen, nitro, C_1-C_5alkyl or C_1-$_5$alkoxy; R_6 and R_7 are each independently H, hydroxyl, halogen, nitro, C_1-$_5$alkylene or C_1-$_5$alkoxy; and R_6 and R_7 may be connected to form a 4- to 8-membered ring;
m and n are each independently integers ranging from 0 to 4; and
X is CH_2, O or S.

2. The amorphous solid dispersion of claim 1, wherein the tetrazole derivative is the compound of formula (II) or (III):



(II);



(III).

3. The amorphous solid dispersion of claim 1, wherein the solid dispersion further comprises a water-soluble polymer.

4. The amorphous solid dispersion of claim 3, wherein the water-soluble polymer is selected from the group consisting of hypromellose, hydroxypropyl cellulose, polyvinylpyrrolidone, polyvinyl acetal, diethyl aminoacetate, polyethylene glycol and a mixture thereof.

5. The amorphous solid dispersion of claim 3, wherein the water-soluble polymer is included in an amount of 0.1 to 4 parts by weight, based on 1 part by weight of the active ingredient.

6. The amorphous solid dispersion of claim 1, wherein the solid dispersion comprises an acid.

7. The amorphous solid dispersion of claim 6, wherein the acid is selected from the group consisting of an inorganic acid such as phosphoric acid, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, boric acid; and an organic acid such as citric acid, malic acid, tartaric acid, lactic acid, tosilate, succinic acid, ascorbic acid, glutamic acid, alginic acid, maleic acid, adipic acid.

8. The amorphous solid dispersion of claim 6, wherein the acid is included in an amount of 0.1 to 3 parts by weight, based on 1 part by weight of the active ingredient.

9. The amorphous solid dispersion of claim 1, wherein the solid dispersion is prepared by using a mixed solution of methylene chloride, ethanol and distilled water in a ratio of methylene chloride : ethanol : distilled water = 0.5 to 0.85 parts

by weight : 0.1 to 0.4 parts by weight : 0.05 to 0.2 parts by weight.

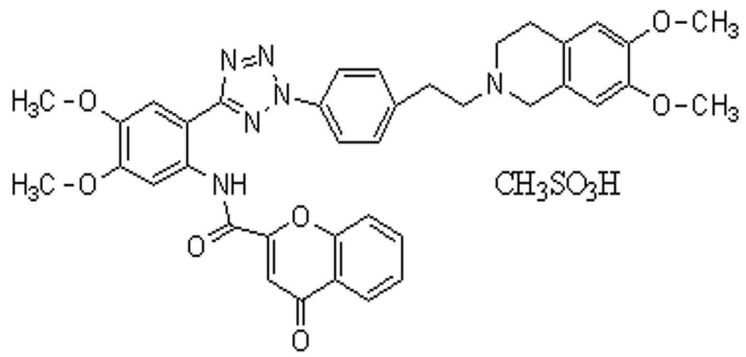
10. The amorphous solid dispersion of claim 1, wherein the average particle diameter of the solid dispersion is less than 150 μm.

11. A pharmaceutical composition comprising the solid dispersion of claim 1.

12. A pharmaceutical composition comprising the solid dispersion of claim 1 and an anti-cancer agent.

13. The pharmaceutical composition of claim 12, wherein the anti-cancer agent is selected from the group consisting of paclitaxel, docetaxel, vincristine, vinblastine, vinorelbine, daunomycin, doxorubicin, topotecan, irinotecan, actinomycin and etopocide.

14. A polymorph of a compound of formula (II), characterized by an X-ray power diffraction pattern comprising peaks at approximately 7.948, 12.936, 14.744, and 26.485 degree two-theta:



(II).

15. The polymorph of claim 14, characterized by an X-ray power diffraction pattern comprising peaks at approximately 4.911, 6.474, 7.948, 9.827, 10.712, 11.522, 12.007, 12.936, 13.498, 14.063, 14.744, 15.282, 15.878, 16.686, 18.66, 19.388, 19.698, 21.065, 23.22, 25.222, 26.485, 26.86 and 28.405 degree two-theta.

16. The polymorph of claim 14, characterized by an X-ray power diffraction pattern substantially similar to the X-ray power diffraction pattern set forth in Figure 3.

17. A solid dispersion comprising the polymorph of claim 14.

18. A pharmaceutical composition comprising the polymorph of claim 14, and a pharmaceutically acceptable carrier.

19. Use of the polymorph of claim 14 and a pharmaceutically acceptable carrier in the manufacture of a medicament for inhibiting a P-glycoprotein.