CLAIMS

1. A hydrate of dimethylaminomicheliolide fumarate, characterized in that, the hydrate is in a crystalline form D, the molar ratio of dimethylaminomicheliolide fumarate to water is 1:1, and the hydrate has a molecular formula of $C_{17}H_{27}NO_3 \cdot C_4H_4O_4 \cdot H_2O$; a thermogravimetric analysis shows a weight loss of 3.97%–4.22% before decomposition; a differential scanning calorimetry pattern shows a dehydration endothermic peak at 75±5 °C and a characteristic melting peak at 148±5 °C.

2. The hydrate of dimethylaminomicheliolide fumarate according to claim 1, characterized in that, the hydrate has characteristic peaks at 2θ angles of 7.8±0.2°, 11.1±0.2°, 11.4±0.2°, 12.6±0.2°, 12.9±0.2°, 14.4±0.2°, 15.3±0.2°, 17.0±0.2°, 18.7±0.2°, 19.7±0.2°, 20.6±0.2°, 21.0±0.2°, 22.5±0.2°, 23.7±0.2°, 24.3±0.2°, 25.5±0.2° and 26.2±0.2° in an X-ray powder diffraction pattern using Cu-Kα radiation, wherein the peak at 7.8±0.2° is an initial peak; the characteristic peak at 20.6±0.2° has a relative intensity of 100%; the crystalline form D is in an orthorhombic crystal system and has a space group of $P2_12_12_1$, a cell parameter of a = 8.8346(18) Å, b = 14.796(3) Å, c= 16.385(3) Å, α = 90°, β = 90°, and γ = 90°; and a cell volume of 2141.8(8) Å3.

3. The hydrate of dimethylaminomicheliolide fumarate according to claim 1, characterized in that, the hydrate also has characteristic peaks at 2θ angles of 10.5±0.2°, 11.7±0.2°, 12.0±0.2°, 15.6±0.2°, 15.9±0.2°, 16.2±0.2°, 21.3±0.2°, 22.1±0.2°, 23.0±0.2°, 26.4±0.2°, 27.2±0.2°, 28.2±0.2°, 28.6±0.2°, 29.3±0.2°, 30.4±0.2° and 31.1±0.2° in an X-ray powder diffraction pattern using Cu-Kα radiation.

4. A preparation method for the hydrate of dimethylaminomicheliolide fumarate according to any one of claims 1–3, characterized in that, the preparation is implemented by reactive crystallization: under the action of stirring, adding dimethylaminomicheliolide and fumaric acid to a mixed solvent system of a solvent S1 and a solvent S2 at a constant temperature of 30 °C–70 °C, with the mass ratio of the solvent S2 to the solvent S1 being (0–3):1 and the molar ratio of dimethylaminomicheliolide to fumaric acid being (1–1.6):1; after 5–10 h of reaction, filtering the reaction mixture and drying the residue at 25–45 °C under normal pressure for 6–10 h to obtain dimethylaminomicheliolide fumarate in a crystalline form D;
the solvent S1 is a mixed solvent of water and any one of acetone, tetrahydrofuran, 1,4-dioxane,

acetonitrile and methyl isobutyl ketone;

the solvent S2 is a mixed solvent of an ester and an ether;

the ester solvent may be selected from any one or two of methyl acetate, ethyl acetate, hexyl acetate and isopropyl acetate;

the ether solvent may be selected from any one or two of diethyl ether, methyl ethyl ether, methyl *tert*-butyl ether, dipropyl ether, dibutyl ether, ethylene glycol dimethyl ether, ethylene glycol monomethyl ether, 1,4-dioxane, tetrahydrofuran and 2-methyl tetrahydrofuran.

5. The preparation method ~~A~~according to claim 4, wherein

the mass ratio of any one of acetone, tetrahydrofuran, 1,4-dioxane, acetonitrile and methyl isobutyl ketone to water in the solvent S1 is (5–10):1;

the mass ratio of the ester solvent to the ether solvent in the solvent S2 is (1–3):1;

the mass ratio of the solid starting material dimethylaminomicheliolide to S1 is 1:(6–10).

6. The hydrate of dimethylaminomicheliolide fumarate according to claim 1 ~~can~~operable to be used to prepare a solventless compound of dimethylaminomicheliolide fumarate in a crystalline form B, wherein the preparation method for the solventless compound of dimethylaminomicheliolide fumarate in the crystalline form B comprises: heating the hydrate of dimethylaminomicheliolide fumarate at a constant temperature of 80 °C–120 °C for 10 min–30 min to obtain the solventless compound of dimethylaminomicheliolide fumarate in the crystalline form B.

7. The hydrate of dimethylaminomicheliolide fumarate according to claim 1 ~~also~~operable to provide~~s~~ a pharmaceutical composition, which comprises a pharmaceutically acceptable auxiliary material and may also comprise one, two or more other pharmacologically active ingredients other than the hydrate of dimethylaminomicheliolide fumarate.

8. The hydrate of dimethylaminomicheliolide fumarate according to claim 7, wherein ~~T~~the pharmaceutically acceptable auxiliary material ~~according to claim 7~~ includes, but is not limited to, other non-pharmacologically active ingredients other than active ingredients~~, such as dimethylaminomicheliolide fumarate in a crystalline form, e.g., non-pharmacologically active ingredients that may be used for the pharmaceutical composition of the present disclosure, including carriers or excipients such as fillers, glidants, lubricants, binders, stabilizers and/or other auxiliary materials;~~

~~the fillers include, but are not limited to, at least one of maize starch, glucose, mannitol, sorbitol, silica, microcrystalline cellulose, sodium carboxymethyl starch, composite starch and pregelatinized starch;~~

~~the glidants include, but are not limited to, at least one of silica, hydrated silica, light anhydrous silicic acid, dry aluminum hydroxide gel, aluminum silicate and magnesium silicate;~~

~~the lubricants include, but are not limited to, at least one of wheat starch, rice starch, maize starch, stearic acid, calcium stearate, magnesium stearate, hydrated silica, light anhydrous silicic acid, synthetic aluminum silicate, dry aluminum hydroxide gel, talc, magnesium aluminometasilicate, dicalcium phosphate, anhydrous dicalcium phosphate, sucrose fatty acid esters, paraffins, hydrogenated vegetable oil and polyethylene glycol~~.

9. The hydrate of dimethylaminomicheliolide fumarate according to claim 7, wherein ~~T~~the pharmaceutical composition ~~according to claim 7~~ is used to prepare a pharmaceutical preparation, characterized in that, the pharmaceutical preparation comprises the pharmaceutical composition in a tablet, capsule or granule dosage form.

10. ~~The present disclosure also provides u~~Use of the hydrate of dimethylaminomicheliolide fumarate according to claim 1 ~~or~~as a pharmaceutical composition in preparing a medicament for the treatment or prevention of~~–~~ a disease or condition, wherein the disease or condition is ~~preferably~~ cancer selected from leukemia, breast cancer, prostate cancer, nasopharyngeal cancer, large intestine cancer, lung cancer, liver cancer, esophageal cancer, gastric cancer, intestinal cancer, renal cancer, oral cancer, Hodgkin's lymphoma, pancreatic cancer, colorectal cancer, cervical cancer, non-Hodgkin's lymphoma, glioma, melanoma, bladder cancer, ovarian cancer, thyroid cancer and Kaposi's sarcoma.