CLAIMS:

1. A quality control (QC) method for a Huashibaidu (HSBD) composition, wherein the HSBD composition mainly comprises the following components: ephedra, fried bitter almond, raw gypsum, licorice, *PogostemonisHerba*, *Magnolia officinalis*, bran-fried *AtractylodesLancea*, fried *Amomum tsaoko* fruit, *RhizomaPinelliae*, *Poriacocos*, *Rheum palmatum*, *Astragalus membranaceus*, *Semen Lepidii*, *Paeoniae Radix Rubra*, and an adjuvant;

wherein the QC method for an HSBD composition comprises:

(1) identifying ephedra, licorice, *Magnolia officinalis Astragalus membranaceus*, *Semen Lepidii*, *Paeoniae Radix Rubra*, *and Rheum palmatum* by thin-layer chromatography (TLC); and

(2) determining a total anthraquinone content, a free anthraquinone content, a total content of ephedrine hydrochloride and pseudoephedrine hydrochloride, and a paeoniflorin content in the HSBD composition by high-performance liquid chromatography (HPLC), and calculating a combined anthraquinone content;

wherein the combined anthraquinone content in the HSBD composition is no less than 0.016%, the total content of ephedrine hydrochloride and pseudoephedrine hydrochloride in the HSBD composition is in a range of 0.7 mg/g to 2.7 mg/g, and the paeoniflorin content in the HSBD composition is in a range of 3 mg/g to 14 mg/g;

wherein the combined anthraquinone content = the total anthraquinone content - the free anthraquinone content;

wherein a determination method of the total anthraquinone content comprises:

(i) weighing appropriate amounts of aloe emodin, rheinic acid, emodin, chrysophanol, and emodin methyl ether, and adding methanol to prepare an anthraquinone reference solution;

(ii) subjecting the HSBD composition to extraction with methanol to prepare a total anthraquinone test solution; and

(iii) injecting the anthraquinone reference solution and the total anthraquinone test solution into a liquid chromatograph with octadecylsilane-bonded silica gel as a filler, and conducting gradient elution with acetonitrile as a mobile phase A and a phosphoric acid aqueous solution as a mobile phase B to determine the total anthraquinone content in the HSBD composition;

wherein a determination method of the free anthraquinone content comprises:

(i') weighing appropriate amounts of aloe emodin, rheinic acid, emodin, chrysophanol, and emodin methyl ether, and adding methanol to prepare an anthraquinone reference solution;

(ii') subjecting the HSBD composition to extraction with methanol to prepare a free anthraquinone test solution; and

(iii') injecting the anthraquinone reference solution and the free anthraquinone test solution into a liquid chromatograph with octadecylsilane-bonded silica gel as a filler, and conducting

gradient elution with acetonitrile as a mobile phase A and a phosphoric acid aqueous solution as a mobile phase B to determine the free anthraquinone content in the HSBD composition; and

wherein in both the determination method of the total anthraquinone content and the determination method of the free anthraquinone content, the following elution program is adopted:

0 min to 10 min: mobile phase A: from 35% to 40%, and mobile phase B: from 65% to 60%;

10 min to 38 min: mobile phase A: from 40% to 60%, and mobile phase B: from 60% to 40%; and

38 min to 48 min: mobile phase A: 60%, and mobile phase B: 40%.

2. The QC method for an HSBD composition according to claim 1, wherein in the determination method of the total anthraquinone content and the determination method of the free anthraquinone content, the octadecylsilane-bonded silica gel is used as a filler, and the gradient elution is conducted with acetonitrile as a mobile phase A and a 0.1 vol% phosphoric acid aqueous solution as a mobile phase B under the following conditions: flow rate: 0.6 mL/min to 1 mL/min, detection wavelength: 253 nm to 256 nm, and column temperature: 25°C to 35°C.

3. The QC method for an HSBD composition according to claim 1, wherein the total anthraquinone test solution is prepared as follows:

adding 0.2 g to 0.5 g of the HSBD composition to an Erlenmeyer flask with a stopper, adding 20 mL to 30 mL of methanol, and heating to allow extraction under reflux for 20 min to 30 min; taking a resulting system out, cooling, weighing, and making up for a weight loss with methanol; thoroughly shaking and filtering the system, and taking 10 mL to 15 mL of a subsequent filtrate; subjecting the subsequent filtrate to vacuum distillation to dryness to obtain a residue and recover methanol, adding 10 mL to 15 mL of a 8% hydrochloric acid solution to the residue, and subjecting a resulting mixture to an ultrasonic treatment for 2 min to 5 min; adding 10 mL to 20 mL of trichloromethane (TCM), and heating to reflux for 1 h to 3 h; cooling a resulting reflux systemand transferringto a separatory funnel, washing a vessel for the refux with a small amount of TCM, and adding the small amount of TCM to the separatory funnel; separating to obtain a primary TCM phase and an acid phase, and subjecting the acid phase to extraction with 10 mL to 15 mL of TCM 2 to 5 times to collect TCM phases and combine with the primary TCM phase, and subjecting a combined TCM phase to vacuum distillation to dryness to obtain a product and recover TCM; dissolving theproduct with methanol, transferring a resulting solution to a 10 mL volumetric flask, and adding methanol to a specified scale; and thoroughly shaking, filtering, and taking a subsequent filtrate as the anthraquinone test solution.

4. The QC method for an HSBD composition according to claim 1, wherein the free anthraquinone test solution is prepared as follows:

adding 0.2 g to 0.5 g of the HSBD composition to an Erlenmeyer flask with a stopper, adding 25 mL to 30 mL of methanol, weighing, and heating to reflux for 20 min to 60 min; taking a resulting system out, cooling, weighing once again, and making up for a weight loss with methanol; and thoroughly shaking, filtering, and taking a subsequent filtrate as the anthraquinone test solution.

5. The QC method for an HSBD composition according to claim 1, wherein the anthraquinone reference solution is prepared as follows:

weighing 1.581 mg of an aloe emodin reference, 3.017 mg of a rheinic acid reference, 1.604 mg of an emodin reference, 2.656 mg of a chrysophanol reference, and 5.221 mg of an emodin methyl ether reference, adding each of the above to a 100 mL volumetric flask respectively, and adding methanol to prepare an aloe emodin stock solution with 15.807 μg of the aloe emodin per mL, a rheinic acid stock solution with 30.167 μg of the rheinic acid per mL, an emodin stock solution with 16.039 μg of the emodin per mL, a chrysophanol stock solution with 26.563 μg of the chrysophanol per mL, and an emodin methyl ether stock solution with 52.213 μg of the emodin methyl ether per mL; and accurately pipetting 1 mL of the aloe emodin stock solution, 1 mL of the rheinic acid stock solution, 1 mL of the emodin stock solution, 1 mL of the chrysophanol stock solution, and 0.1 mL of the emodin methyl ether stock solution to a 10 mL volumetric flask, and adding methanol to prepare a mixed solution with 1.581 μg of the aloe emodin, 3.017 μg of the rheinic acid, 1.604 μg of the emodin, 2.656 μg of the chrysophanol, and 0.522 μg of the emodin methyl ether per mL.

6. The QC method for an HSBD composition according to claim 1, wherein a determination method of the total content of ephedrine hydrochloride and pseudoephedrine hydrochloride comprises:

(1) weighing an appropriate amount of an ephedrine hydrochloride reference and an appropriate amount of a pseudoephedrine hydrochloride reference, and adding methanol to prepare an ephedrine reference solution with 10 μg of the ephedrine hydrochloride reference and 10 μg of the pseudoephedrine hydrochloride reference per mL;

(2) subjecting the HSBD composition to extraction with a hydrochloric acid solution to prepare an ephedrine test solution; and

(3) injecting the ephedrine reference solution and the ephedrine test solution into a liquid chromatograph with polar diethyl ether-linked phenyl-bonded silica gel as a filler, and conducting

elution with a mixed solution of methanol and a phosphoric acid aqueous solution as a mobile phase at a flow rate of 0.6 mL/min to 1 mL/min, a column temperature of 25°C to 35°C, and a detection wavelength of 205 nm to 215 nm to determine the total content of ephedrine hydrochloride and pseudoephedrine hydrochloride in the HSBD composition.

7. The QC method for an HSBD composition according to claim 6, wherein in the determination method of the total content of ephedrine hydrochloride and pseudoephedrine hydrochloride, the mixed solution of methanol and a phosphoric acid aqueous solution is adopted as a mobile phase; and

the phosphoric acid aqueous solution is a mixed solution of phosphoric acid, diethylamine (DEA), triethylamine (TEA), and water, in which a volume fraction of the phosphoric acid is 0.090% to 0.094%, a volume fraction of the DEA is 0.01% to 0.04%, and a volume fraction of the TEA is 0.02% to 0.06%.

8. The QC method for an HSBD composition according to claim 1, wherein a determination method of the paeoniflorin content comprises:

(1) weighing an appropriate amount of a paeoniflorin reference, and adding methanol to prepare a paeoniflorin reference solution with 0.13 mg of the paeoniflorin reference per mL;

(2) subjecting the HSBD composition to extraction with methanol to prepare a paeoniflorin test solution; and

(3) injecting the paeoniflorin reference solution and the paeoniflorin test solution into a liquid chromatograph with octadecyl-bonded silica gel as a filler, and conducting elution with a methanol-0.05 mol/L monopotassium phosphate (MKP) aqueous solution as a mobile phase at a flow rate of 0.8 mL/min to 1.2 mL/min, a detection wavelength of 225 nm to 230 nm, and a column temperature of 30°C to 35°C to determine the paeoniflorin content in the HSBD composition.

9. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the ephedra comprises:

(1) grinding 5 g to 10 g of the HSBD composition, adding 3 mL to 5 mL of a concentrated ammonia solution for wetting, adding 25 mL to 30 mL of TCM, and heating to reflux for 0.5 h to 1 h; and filtering a resulting system, subjecting a filtrate to evaporation to dryness to obtain a residue, and dissolving theresidue with 1 mL to 2 mL of methanol to obtain an ephedra test solution;

(2) taking an ephedrine hydrochloride reference, and adding methanol to prepare an ephedra reference solution with 1 mg of the ephedrine hydrochloride reference per mL; and

(3) spotting 1 μL to 5 μL of each of the ephedra test solution and the ephedra reference solution

on a same silica gel G TLC plate, and developing with a mixed solution of TCM, methanol, and a concentrated ammonia solution in a volume ratio of 20:5:0.5 as a developing agent; and taking the silica gel G TLC plate out, air-drying, spraying with a ninhydrin solution, and heating until stained spots are clearly visulized, wherein a spot at a position in a chromatogram of the test solution is in the same color as a spot at a corresponding position in a chromatogram of the reference solution.

10. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the licorice comprises:

(1) grinding 5 g to 10 g of the HSBD composition, adding 40 mL to 50 mL of diethyl ether, and heating to reflux for 1 h to 2 h; filtering a resulting system to obtain an ether solution and a filter residue, discarding the ether solution, dissolving the filter residue with 30 mL to 50 mL of methanol, and heating to reflux for 0.5 h to 1.5 h; filtering a resulting reflux system, subjecting a filtrate to evaporation to dryness to obtain a residue, dissolving the residue with 40 mL to 50 mL of water, and subjecting a resulting solution to extraction with 20 mL to 40 mL of n-butanol under shaking 1 to 3 times to collect n-butanol phases; combining the n-butanol phases, washing a combined n-butanol phase with water 1 to 3 times to obtain a n-butanol liquid, and discarding resulting aqueous phases; and evaporating the n-butanolliquidto dryness to obtain a product, and dissolving the product with 5 mL to 10 mL of methanol to obtain a licorice test solution;

(2) taking 1 g to 3 g of a licorice reference, and preparing a licorice reference solution according to the preparation of the licorice test solution in step (1); and

(3) spotting 2 μL to 5 μL of each of the licorice test solution and the licorice reference solution on a same silica gel G TLC plate prepared with a 1% sodium hydroxide solution, and developing with a mixed solution of ethyl acetate, formic acid, glacial acetic acid, and water in a volume ratio of 15:1:1:2 as a developing agent; and taking the silica gel G TLC plate out, air-drying, spraying with a 10% sulfuric acid-ethanol solution, and heating at 100°C to 110°C until stained spots are clearly visulized, wherein a spot at a position in a chromatogram of the test solution is in the same color as a spot at a corresponding position in a chromatogram of the reference solution.

11. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the *Magnolia officinalis* comprises:

(1) grinding 5 g to 10 g of the HSBD composition, adding 15 mL to 25 mL of methanol, and subjecting a resulting mixture to an ultrasonic treatment for 0.5 h to 1 h; filtering a resulting system, subjecting a filtrate to evaporation to dryness to obtain a resuidue, dissolving the residue with 40 mL to 50 mL of water, and subjecting a resulting solution to extraction with 20 mL to 30 mL of ethyl acetate under shaking 1 to 3 times to collect ethyl acetate phases; and combining the ethyl

acetate phases, subjecting a combined ethyl acetate phase to evaporation to dryness to obtain a product, and dissolving the product with 1 mL to 2 mL of methanol to obtain a *Magnolia officinalis* test solution;

(2) taking a magnolol reference, and adding methanol to prepare a magnolol reference solution with 1 mg of the magnolol reference per mL; and taking a honokiol reference, and adding methanol to prepare a honokiol reference solution with 1 mg of the honokiol reference per mL; and

(3) spotting 2 μL to 5 μL of each of the *Magnolia officinalis* test solution, the magnolol reference solution, and the honokiol reference solution on a same silica gel G TLC plate, and developing with a mixed solution of toluene, ethyl acetate, and methanol in a volume ratio of 17:3:3 as a developing agent; and taking the silica gel G TLC plate out, air-drying, spraying with a 5% vanillin-sulfuric acid solution, and heating until stained spots are clearly visulized, wherein a spot at a position in a chromatogram of the test solution is in the same color as a spot at a corresponding position in a chromatogram of the reference solution.

12. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the *Astragalus membranaceus* comprises:

(1) taking 5 g to 10 g of the HSBD composition, adding 25 mL to 30 mL of methanol, and subjecting a resulting mixture to an ultrasonic treatment for 0.5 h to 1 h; cooling and filtering a resulting system, subjecting a filtrate to evaporation to dryness to obtain a residue, dissolving the residue with 20 mL to 30 mL of water, and subjecting a resulting solution to extraction with 15 mL to 30 mL of water-saturated n-butanol under shaking 1 to 3 times to collect n-butanol phases; combining the n-butanol phases, washing a combined n-butanol phase with 20 mL to 30 mL of an ammonia solution 1 to 3 times to obtain a n-butanol liquid, and discarding resulting ammonia phases; and evaporating the n-butanolliquidto dryness to obtain a product, and dissolving the product with 1 mL to 3 mL of methanol to obtain an *Astragalus membranaceus* test solution;

(2) taking an astragaloside reference, and adding methanol to prepare an *Astragalus membranaceus* reference solution with 1 mg of the astragaloside reference per mL; and

(3) spotting 5 μL to 8 μL of the *Astragalus membranaceus* test solution and 2 μL to 3 μL of the *Astragalus membranaceus* reference solution on a same silica gel G TLC plate, and developing at 4°C to 10°C with a mixed solution of TCM, methanol, and water in a volume ratio of 13:7:2 as a developing agent; and taking the silica gel G TLC plate out, air-drying, spraying with a 10% sulfuric acid-ethanol solution, heating at 100°C to 105°C until stained spots are clearly visulized, and observing under ultraviolet (UV) light, wherein a fluorescent spot at a position in a chromatogram of the test solution is in the same color as a fluorescent spot at a corresponding position in a chromatogram of the reference solution.

13. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the *Semen Lepidii* comprises:

(1) grinding 5 g to 10 g of the HSBD composition, adding 20 mL to 30 mL of 70% methanol, and subjecting a resulting mixture to an ultrasonic treatment for 0.5 h to 1 h; cooling and filtering a resulting system, subjecting a filtrate to evaporation to drynessto obtain a residue, and dissolving the residue with 5 mL to 10 mL of water; allowing a resulting solution to pass through a D101 macroporous resin column, eluting with water until an eluate is colorless, eluting with 70% methanol until an 70% methanol eluate is colorless, and collecting the 70% methanol elute; and subjecting the 70% methanol eluate to evaporation to dryness to obtain a product, and dissolving the product with 1 mL to 2 mL of methanol to obtain a *Semen Lepidii* test solution;

(2) taking a quercetin-3-O-β-D-glucose-7-O-β-D-gentiobioside reference, and adding 30% methanol to prepare a *Semen Lepidii* reference solution with 0.1 mg of the quercetin-3-O-β-D-glucose-7-O-β-D-gentiobioside reference per mL; and

(3) spotting 1 μL to 5 μL of each of the *Semen Lepidii* test solution and the *Semen Lepidii*reference solution on a same polyamide (PA) film, and developing with a mixed solution of ethyl acetate, methanol, and water in a volume ratio of 7:2:1 as a developing agent; and taking the PA film out, air-drying, spraying with a 2% aluminum chloride-ethanol solution, hot air-drying, and observing under UV light, wherein a fluorescent spot at a position in a chromatogram of the test solution is in the same color as a fluorescent spot at a corresponding position in a chromatogram of the reference solution.

14. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the *Paeoniae Radix Rubra* comprises:

(1) grinding 3 g to 5 g of the HSBD composition, adding 25 mL to 40 mL of methanol, and subjecting a resulting mixture to an ultrasonic treatment for 0.5 h to 1 h; and filtering a resulting system, subjecting a filtrate to evaporation to drynessto obtain a residue, and dissolving the residue with 1 mL to 2 mL of methanol to obtain a *Paeoniae Radix Rubra* test solution;

(2) taking a paeoniflorin reference, and adding methanol to prepare a *Paeoniae Radix Rubra* reference solution with 1 mg of the paeoniflorin reference per mL; and

(3) spotting 2 μL to 5 μL of each of the *Paeoniae Radix Rubra* test solution and the *Paeoniae Radix Rubra* reference solution on a same silica gel G TLC plate, and developing with a mixed solution of TCM, ethyl acetate, methanol, and formic acid in a volume ratio of 40:5:10:0.2 as a developing agent; and taking the silica gel G TLC plate out, air-drying, spraying with a 5% vanillin-sulfuric acid solution, and heating until stained spots are clearly visulized, wherein a spot

at a position in a chromatogram of the test solution is in the same color as a spot at a corresponding position in a chromatogram of the reference solution.

15. The QC method for an HSBD composition according to claim 1, wherein a TLC identification method for the *Rheum palmatum* comprises:

(1) grinding 5 g to 10 g of the HSBD composition, adding 20 mL to 30 mL of methanol, and subjecting a resulting mixture to an ultrasonic treatment for 20 min to 30 min; filtering a resulting system, and taking 3 mL to 10 mL of a filtrate; subjecting the filtrate to evaporation to dryness to obtain a residue, dissolving the residue with 5 mL to 15 mL of water, adding 1 mL to 3 mL of hydrochloric acid, and heating to reflux for 20 min to 60 min; immediately cooling a resulting reflux system, and subjecting the refluxsystem to extraction with 20 mL to 30 mL of diethyl ether under shaking 2 to 3 timestocollect diethyl ether phases; and combining the diethyl ether phases, subjecting a combined diethyl ether phase to evaporation to dryness to obtain a product, and dissolving the product with 1 mL to 3 mL of TCM to obtain a *Rheum palmatum* test solution;

(2) taking 0.1 g of a *Rheum palmatum* reference, and preparing a *Rheum palmatum* reference solution according to the preparation of the *Rheum palmatum* test solution in step (1); and

(3) spotting 1 μL to 5 μL of each of the *Rheum palmatum* test solution and the *Rheum palmatum* reference solution on a same silica gel H TLC plate, and developing with a mixed solution of petroleum ether, ethyl formate, and formic acid in a volume ratio of 15:5:1 as a developing agent; and taking the silica gel H TLC plate out, air-drying, and observing under UV light, wherein a fluorescent spot at a position in a chromatogram of the test solution is in the same color as a fluorescent spot at a corresponding position in a chromatogram of the reference solution.

16. The QC method for an HSBD composition according to claim 1, wherein the HSBD composition mainly comprises the following components: 3 to 60 parts of the ephedra, 4.5 to 90 parts of the fried bitter almond, 7.5 to 150 parts of the raw gypsum, 1.5 to 30 parts of the licorice, 5 to 100 parts of the *PogostemonisHerba*, 5 to 100 parts of the *Magnolia officinalis*, 7.5 to 150 parts of the bran-fried *AtractylodesLancea*, 5 to 100 parts of the fried *Amomum tsaoko* fruit, 4.5 to 90 parts of the *RhizomaPinelliae*, 7.5 to 150 parts of the *Poriacocos*, 2.5 to 50 parts of the *Rheum palmatum*, 5 to 100 parts of the *Astragalus membranaceus*, 5 to 100 parts of the *Semen Lepidii*, 5 to 100 parts of the *Paeoniae Radix Rubra*, and an appropriate amount of the adjuvant; and

the HSBD composition is prepared into a traditional Chinese medicine (TCM) preparation in a form selected from the group consisting of a granule, a decoction, a powder, a capsule, an oral liquid, a tablet, and a pill.