amount of puerarin ($C_{21}H_{20}O_9$).

Description A white to slightly yellow mass or powder.

Identification (1) Dissolve a quantity of the substance being examined (equivalent to 10 mg puerarin) in 10 ml of water. Add 2-3 drops of hydrochloric acid and adjust to pH acidic. Add 2-3 drops of 0.5% ferric chloride solution and mix well, then add 2-3 drops of 0.5% potassium ferricyanide solution, mix well, a blue-green colour is produced.

(2) The retention times of the principal peaks in the chromatogram of the test solution obtained in the Assay are identical with those of the principal peaks in the chromatogram of the reference solution.

Alkalinity An aqueous solution of 1 mg puerarin per ml, pH 7.5-9.0 〈*0631*〉.

Clarity and colour of solution Add the labelled amount of water to 5 vials respectively to produce a solution of 1 mg puerarin per ml, the solution is clear and colourless; any colour produced is not more intense than that of reference solution Y_1 〈*0901*, *method 1*〉.

Related substances Carry out the method for high performance liquid chromatography 〈*0512*〉.

Test solution Dilute a quantity in solvent to produce a solution containing 0.5 mg puerarin per ml.

Reference solution Accurately measure a quantity of test solution, dilute with the solvent to produce a solution of 5 μg puerarin per ml.

Solvent, *System suitability solution*, *Chromatographic conditions*, *System suitability requirement* and *Procedure* Proceed as described in the test for Related substances under Puerarin.

Limits The area of any other impurity peak obtained with the test solution is not greater than the area of the principal peak in the chromatogram obtained with the reference solution (1.0%); The sum of the area of all peaks other than the principal peak obtained with the test solution is not greater than 2 times the area of the principal peak in the chromatogram obtained with the reference solution (2.0%).

Loss on drying When dried to constant weight at 105℃, loses not more than 5.0% of its weight 〈*0831*〉.

Undue toxicity Complies with the test for undue toxicity 〈*1141*〉, using a solution of 10 mg puerarin per ml prepared by diluting with Sodium Chloride Injection.

Bacterial endotoxins Carry on the test for bacterial endotoxins 〈*1143*〉: less than 0.17 EU per mg of puerarin.

Allergic reaction Complies with the test for allergic reaction 〈*1147*〉, using a solution of 50 mg puerarin per ml prepared by diluting with Sodium Chloride Injection.

Hemolysis and cohesion Complies with the test for hemolysis and cohesion 〈*1148*〉, using a solution of 20 mg puerarin per ml prepared by diluting with Sodium Chloride Injection.

Other requirements Complies with the general requirements for injections 〈*0102*〉.

Assay Carry out the method for high performance liquid chromatography 〈*0512*〉.

Test solution Mix the contents obtained in the test for Weight variation, dissolve a quantity, accurately weighed, in the mobile phase to produce a solution of 50 μg puerarin per ml.

Reference solution, *Chromatographic conditions*, *System suitability requirements* and *Procedure* Proceed as described in the Assay under Puerarin.

Category As described under Puerarin.

Strength (1) 50 mg (2) 0.1 g (3) 0.2 g (4) 0.4 g

Storage Preserved in well closed containers, protected from light.

Purified Water

H_2O 18.02

Purified Water is prepared from drinking water by ditillation, ion exchange, reverse osmosis or by means of any other appropriate methods. It contains no additives.

Description A clear, colourless liquid, odourless.

Acidity or alkalinity To 10 ml add 2 drops of methyl red IS, no red colour is produced. To another 10 ml add 5 drops of bromothymol blue IS, no blue colour is produced.

Nitrate To 5 ml in a test tube, cooled in an ice bath, add 0.4 ml of 10% potassium chloride solution and 0.1 ml of 0.1% diphenylamine solution in sulfuric acid and shake well. Add 5 ml of sulfuric acid dropwise and allow to stand in a water bath at 50℃ for 15 minutes. Any colour produced is not more intense than that of the reference solution (Dissolve a quantity of potassium nitrate in water to produce a solution containing 1 μg of NO_3 per ml. To 0.3 ml add 4.7 ml of nitrate-free water, repeat the operation using the solution instead of the substance being examined) (0.000006%).

Nitrite To 10 ml in a Nessler cylinder add 1 ml of sulfanilic amide solution (dissolve 1 g in 100 ml of dilute hydrochloric acid) and 1 ml of 0.1% *N*-naphthylethylenediamine dihydrochloride solution and shake well. Any colour produced is not more intense than that of the reference solution (Dissolve a quantity of sodium nitrite in water to produce a solution containing 1 μg of NO_2 per ml. To 0.2 ml add 9.8 ml of nitrite-free water, repeat the operation using the solution instead of the substance being examined) (0.000002%).

Ammonia To 50 ml add 2 ml of alkaline mercuric potassium iodide TS and allow to stand for 15 minutes. Any colour produced is not more intense than that of a reference prepared by mixing 1.5 ml of ammonium chloride solution (dissolve 31.5 mg of ammonium chloride CRS in ammonia-free distilled water to produce 1000 ml) with 48 ml of ammonia-free distilled water and 2 ml of alkaline mercuric potassium iodide TS (0.00003%).

Conductivity Complies with the test for water conductivity 〈*0681*〉.

Total organic carbon Not more than 0.50 mg per L 〈*0682*〉.

Oxidizable substances Boil 100 ml with 10 ml of dilute sulphuric acid, add 0.10 ml of potassium permanganate (0.02 mol/L) VS and continue to boil for 10 minutes; the pink colour does not disappear completely.

Total organic carbon and Oxidizable substances may be used alternatively.

Non-volatile substances Evaporate 100 ml in an evaporating dish previously dried at 105℃ to constant weight, to dryness on a water bath, dry at 105℃ to constant weight, the residue is not more than 1 mg.

Heavy metals To 100 ml add 19 ml of water, evaporate to 20 ml, cool. Add 2 ml of acetate BS (pH 3.5) and a quantity of water to 25 ml. Add 2 ml of thioacetamide TS, mix and allow to stand for 2 minutes. Any colour produced is not more intense than that of the solution prepared in the same manner using 1.0 ml of lead standard solution mixed with 19 ml of water (0.00001%).

Microbial limit Complies with microbiological examination of non-sterile products: microbial enumeration tests 〈*1105*, *membrane filtration method*〉, using at least 1 ml, using R2A agar and incubating at 30-35℃ for not less than 5 days. The number of aerobic microbial count is not more than 100 cfu per ml.

R2A agar

Yeast extract	0.5 g
Proteose peptone	0.5 g
Casein hydrolysate	0.5 g
Glucose	0.5 g
Starch	0.5 g
Dipotassium hydrogen phosphate	0.3 g
Magnesium sulfate, anhydrous	0.024 g
Sodium pyruvate	0.3 g
Agar	15 g
Purified water	1000 ml

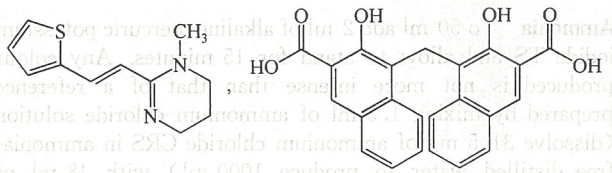
Mix the above ingredients in water except for glucose and agar, warming slightly until the substances are dissolved. Adjust the pH so that after heating it is 7.2 ± 0.2 at 25℃. Add agar, heat until melted and then add glucose, shake thoroughly, dispense and sterilize.

Suitability test for R2A agar Carry out the method described under growth promotion of soya bean casein digest agar in Growth Promotion of the Counting Media, Pseudomonas aeruginosa and Bacillus subtilis as test strain, complies with the microbiological examination of non-sterile products: microbial enumeration tests 〈*1105*〉.

Category Solvent and diluent.

Storage Preserve in well closed containers.

Pyrantel Pamoate



$C_{11}H_{14}N_2S \cdot C_{23}H_{16}O_6$ 594.68 [22204-24-6]

Pyrantel Pamoate is (*E*)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)ethenyl]pyrimidine-4,4'-methylene-bis[3-hydroxy-2-naph-thalenecarboxylic acid (1:1)]. It contains not less than 97.0% and not more than 103.0% of $C_{11}H_{14}N_2S \cdot C_{23}H_{16}O_6$, calculated on the dried basis.

Description A pale yellow powder; odourless. Sparingly soluble in *N*, *N*-dimethylformamide; very slightly soluble in ethanol; practically insoluble in water.

Specific absorbance Protect from light throughout the procedure. Dissolve about 20 mg, accurately weighed, in 8 ml of a mixture of dioxane and 0.1% ammonia solution (1:1). Dilute with hydrochloric acid solution (9→1000) to 100 ml, and mix well, filter. Accurately measure 5 ml of the successive filtrate, dilute with a hydrochloric acid solution (9→1000) to 50 ml. Measure the absorbance of the resulting solution at 311 nm 〈*0401*〉, the value of *A* (1%, 1 cm) is 302-324.

Identification (1) Dissolve about 10 mg in 5 ml of a mixture of dioxane-0.1% concentrated ammonia solution (1:1), add 2 ml of dilute hydrochloric acid; a yellow precipitate is produced.

(2) To about 20 mg add 1 ml of sulfuric acid and shake; a red colour is produced.

(3) The retention times of principal peaks of the substance being examined in the chromatogram obtained in the Assay are identical with those of principal peaks of pyrantel pamoate CRS.

(4) The infrared absorption spectrum 〈*0402*〉 is concordant with the reference spectrum of pyrantel pamoate (IR Album No. 51).

Chlorinated compounds Carry out the method for oxygen flask combustion 〈*0703*〉, using 25 mg, with 10 ml of 0.4% sodium hydroxide solution as the absorbing liquid until absorption is complete. Carry out the limit test for chlorides 〈*0801*〉, using the resulting solution. Any opalescence produced is not more pronounced than that of a reference using 3.5 ml of sodium chloride standard solution (0.14%).

Pamoic acid Carry out the method for high performance liquid chromatography 〈*0512*〉.

Test solution Proceed as described in the test under Assay.

Reference solution Dissolve a quantity of pamoic acid CRS dried in vacuum for 3 hours at 60℃, accurately measured, in the mobile phase and dilute to produce a solution containing about 52 μg per ml.

Chromatographic conditions Proceed as described in the test under Assay.

Procedure Inject separately the test solution and reference solution into the chromatograph and record the chromatograms. Calculate the contents of $C_{23}H_{16}O_6$ with respect to the peak area obtained in the chromatogram by external standard method.

Limits Not less than 63.4% and not more than 67.3%, calculated on the dried basis.

Related substances Carry out the method for high performance liquid chromatography 〈*0512*〉. Protect from light throughout the procedure. Prepare the solutions immediately before use.

Test solution Transfer 80 mg of the substance being examined to a 100 ml volumetric flask, add 7ml of a mixture solvent of glacial acetic acid-water-diethylamine (5:5:2) to dissolve and dilute with acetonitrile to volume, and mix well.

Reference solution Transfer 1 ml of the test solution, accurately measured, to a 100 ml volumetric flask, dilute with mobile phase to volume, and mix well.

System suitability solution Expose 10 ml of the test solution under Assay to the light with illumination in tensity of 2000 lx for 24 hours.

Chromatographic conditions Use a column packed with silica gel and acetonitriel-water-acetic acid-diethylamine (92.8:3:3:1.2) as the mobile phase. The detection wavelength is 288 nm. The injection volume is 20 μl.