Aromatic Castor Oil

加香ヒマシ油

Method of preparation

Castor Oil	990 mL
Orange Oil	5 mL
Mentha Oil	5 mL
To make	1000 mL

Mix the above ingredients.

Description Aromatic Castor Oil is a colorless or yellowish, clear, viscous liquid. It has an aromatic odor.

Identification To 3 g of Aromatic Castor Oil add 1 g of potassium hydroxide, and heat the mixture carefully to fuse: a characteristic odor is perceptible. Dissolve the fused matter in 30 mL of water, add an excess of magnesium oxide, and filter. Acidify the filtrate with hydrochloric acid: white crystals are produced.

Containers and storage Containers—Tight containers.

Catalpa Fruit

Catalpae Fructus

キササゲ

Catalpa Fruit is the fruit of *Catalpa ovata* G. Don or *Catalpa bungei* C. A. Meyer (*Bignoniaceae*).

Description Slender stick-like fruit, 30 – 40 cm in length and about 0.5 cm in diameter; externally, dark brown; inner part contains numerous seeds; seed compressed or semitubular, about 3 cm in length and about 0.3 cm in width, externally grayish brown; hairs, about 1 cm in length, attached to both ends of seed; pericarp, thin and brittle. Almost odorless; taste, slightly astringent.

Identification To 1.0 g of pulverized Catalpa Fruit add 20 mL of water, warm on a water bath for 5 minutes, and filter immediately. Transfer the filtrate to a separator, and extract with two 20-mL portions of 1-butanol. Combine the extracts, evaporate the 1-butanol on a water bath, dissolve the residue in 1 mL of methanol, and use this solution as the sample solution. Separately, dissolve 1 mg of parahydroxybenzoic acid in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5) and water (20:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultra-violet light (main wavelength: 254 nm): one spot among the spots from the sample solution and a dark purple spot from the standard solution show the same color tone and the same *Rf* value. Prescribe that the moving distance of the spot corresponding to parahydroxybenzoic acid from the sample solution is 1: a dark purple spot develops at the relative moving distance of about 0.3.

Purity Peduncle—The amount of peduncles contained in Catalpa Fruit does not exceed 5.0%.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 0.5%.

Extract content Dilute ethanol-soluble extract: not less than 8.0%.

Microcrystalline Cellulose

結晶セルロース

Microcrystalline Cellulose is purified, partially depolymerized α-cellulose, obtained as a pulp from fibrous plant material, with mineral acids.

The label indicates the degree of polymerization, loss on drying, and bulk density values with the range.

Description Microcrystalline Cellulose occurs as a white crystalline powder having fluidity.

It is practically insoluble in water, in ethanol (95) and in diethyl ether.

It swells with sodium hydroxide TS on heating.

Identification **(1)** Dissolve 20 g of zinc chloride and 6.5 g of potassium iodide in 10.5 mL of water, add 0.5 g of iodine, and shake for 15 minutes. Place about 10 mg of Microcrystalline Cellulose on a watch glass, and disperse in 2 mL of this solution: the substance develops a blue-violet color.

(2) Sieve 20 g of Microcrystalline Cellulose for 5 minutes on an air-jet sieve equipped with a screen (No.391, 200 mm in inside diameter) having 38-μm openings. If more than 5% is retained on the screen, mix 30 g of Microcrystalline Cellulose with 270 mL of water; otherwise, mix 45 g with 255 mL of water. Perform the mixing for 5 minutes in a high-speed (18,000 revolutions per minute or more) power blender. Transfer 100 mL of the dispersion to a 100-mL graduated cylinder, and allow to stand for 3 hours: a white, opaque, bubble-free dispersion, which does not form a supernatant liquid at the surface, is obtained.

(3) Transfer 1.3 g of Microcrystalline Cellulose, accurately weighed, to a 125-mL conical flask, and add exactly 25 mL each of water and 1 mol/L cupriethylenediamine TS. Immediately purge the solution with nitrogen, insert the stopper, and shake on a suitable mechanical shaker to dissolve. Perform the test with this solution according to Method 1 under the Viscosity Determination using a capillary viscometer having the viscosimeter constant (*K*), 0.03, at 25 ± 0.1°C, and determine the kinematic viscosity, *v*. Separately, perform the test with a mixture of exactly 25 mL each of water and 1 mol/L cupriethylenediamine TS in the same manner as above, using a capillary viscometer having *K*, 0.01, and determine the kinematic viscosity, v_0.

Calculate the relative viscosity, η_{rel}, of Microcrystalline Cellulose by the formula:

$$\eta_{rel} = \frac{v}{v_0}$$

Obtain the product, $[\eta]C$, of limiting viscosity $[\eta]$(mL/g)

and concentration C (g/100 mL) from the value η_{rel} of the Tableshown somewhere below. When calculate the degree of polymerization, P, by the following formula, P is not more than 350 and within the labeled range.

$$P = \frac{(95)[\eta]C}{\text{amount (g) of the sample, calculated on the dried basis}}$$

pH Shake 5.0 g of Microcrystalline Cellulose with 40 mL of recently boiled and cooled water for 20 minutes, and centrifuge: the pH of the supernatant liquid is between 5.0 and 7.0.

Purity (1) Water-soluble substances—Shake 5.0 g of Microcrystalline Cellulose with 80 mL of water for 10 minutes, filter with the aid of vacuum through filter paper

Table for Conversion of Relative Viscosity (η_{rel}) into the Product of Limiting Viscosity and Concentration ($[\eta]C$)

	$[\eta]C$									
η_{rel}	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
1.1	0.098	0.106	0.115	0.125	0.134	0.143	0.152	0.161	0.170	0.180
1.2	0.189	0.198	0.207	0.216	0.225	0.233	0.242	0.250	0.259	0.268
1.3	0.276	0.285	0.293	0.302	0.310	0.318	0.326	0.334	0.342	0.350
1.4	0.358	0.367	0.375	0.383	0.391	0.399	0.407	0.414	0.422	0.430
1.5	0.437	0.445	0.453	0.460	0.468	0.476	0.484	0.491	0.499	0.507
1.6	0.515	0.522	0.529	0.536	0.544	0.551	0.558	0.566	0.573	0.580
1.7	0.587	0.595	0.602	0.608	0.615	0.622	0.629	0.636	0.642	0.649
1.8	0.656	0.663	0.670	0.677	0.683	0.690	0.697	0.704	0.710	0.717
1.9	0.723	0.730	0.736	0.743	0.749	0.756	0.762	0.769	0.775	0.782
2.0	0.788	0.795	0.802	0.809	0.815	0.821	0.827	0.833	0.840	0.846
2.1	0.852	0.858	0.864	0.870	0.876	0.882	0.888	0.894	0.900	0.906
2.2	0.912	0.918	0.924	0.929	0.935	0.941	0.948	0.953	0.959	0.965
2.3	0.971	0.976	0.983	0.988	0.994	1.000	1.006	1.011	1.017	1.022
2.4	1.028	1.033	1.039	1.044	1.050	1.056	1.061	1.067	1.072	1.078
2.5	1.083	1.089	1.094	1.100	1.105	1.111	1.116	1.121	1.126	1.131
2.6	1.137	1.142	1.147	1.153	1.158	1.163	1.169	1.174	1.179	1.184
2.7	1.190	1.195	1.200	1.205	1.210	1.215	1.220	1.225	1.230	1.235
2.8	1.240	1.245	1.250	1.255	1.260	1.265	1.270	1.275	1.280	1.285
2.9	1.290	1.295	1.300	1.305	1.310	1.314	1.319	1.324	1.329	1.333
3.0	1.338	1.343	1.348	1.352	1.357	1.362	1.367	1.371	1.376	1.381
3.1	1.386	1.390	1.395	1.400	1.405	1.409	1.414	1.418	1.423	1.427
3.2	1.432	1.436	1.441	1.446	1.450	1.455	1.459	1.464	1.468	1.473
3.3	1.477	1.482	1.486	1.491	1.496	1.500	1.504	1.508	1.513	1.517
3.4	1.521	1.525	1.529	1.533	1.537	1.542	1.546	1.550	1.554	1.558
3.5	1.562	1.566	1.570	1.575	1.579	1.583	1.587	1.591	1.595	1.600
3.6	1.604	1.608	1.612	1.617	1.621	1.625	1.629	1.633	1.637	1.642
3.7	1.646	1.650	1.654	1.658	1.662	1.666	1.671	1.675	1.679	1.683
3.8	1.687	1.691	1.695	1.700	1.704	1.708	1.712	1.715	1.719	1.723
3.9	1.727	1.731	1.735	1.739	1.742	1.746	1.750	1.754	1.758	1.762
4.0	1.765	1.769	1.773	1.777	1.781	1.785	1.789	1.792	1.796	1.800
4.1	1.804	1.808	1.811	1.815	1.819	1.822	1.826	1.830	1.833	1.837
4.2	1.841	1.845	1.848	1.852	1.856	1.859	1.863	1.867	1.870	1.874
4.3	1.878	1.882	1.885	1.889	1.893	1.896	1.900	1.904	1.907	1.911
4.4	1.914	1.918	1.921	1.925	1.929	1.932	1.936	1.939	1.943	1.946
4.5	1.950	1.954	1.957	1.961	1.964	1.968	1.971	1.975	1.979	1.982
4.6	1.986	1.989	1.993	1.996	2.000	2.003	2.007	2.010	2.013	2.017
4.7	2.020	2.023	2.027	2.030	2.033	2.037	2.040	2.043	2.047	2.050
4.8	2.053	2.057	2.060	2.063	2.067	2.070	2.073	2.077	2.080	2.083
4.9	2.087	2.090	2.093	2.097	2.100	2.103	2.107	2.110	2.113	2.116
5.0	2.119	2.122	2.125	2.129	2.132	2.135	2.139	2.142	2.145	2.148
5.1	2.151	2.154	2.158	2.160	2.164	2.167	2.170	2.173	2.176	2.180
5.2	2.183	2.186	2.190	2.192	2.195	2.197	2.200	2.203	2.206	2.209
5.3	2.212	2.215	2.218	2.221	2.224	2.227	2.230	2.233	2.236	2.240
5.4	2.243	2.246	2.249	2.252	2.255	2.258	2.261	2.264	2.267	2.270
5.5	2.273	2.276	2.279	2.282	2.285	2.288	2.291	2.294	2.297	2.300
5.6	2.303	2.306	2.309	2.312	2.315	2.318	2.320	2.324	2.326	2.329
5.7	2.332	2.335	2.338	2.341	2.344	2.347	2.350	2.353	2.355	2.358
5.8	2.361	2.364	2.367	2.370	2.373	2.376	2.379	2.382	2.384	2.387
5.9	2.390	2.393	2.396	2.400	2.403	2.405	2.408	2.411	2.414	2.417
6.0	2.419	2.422	2.425	2.428	2.431	2.433	2.436	2.439	2.442	2.444

into a vacuum flask. Evaporate the clear filtrate in a tared evaporating dish to dryness without charring, dry at 105°C for 1 hour, cool in a desiccator (silica gel), and weigh: the difference between the mass of the residue and the mass obtained from a blank determination does not exceed 12.0 mg.

(2) Diethyl ether-soluble substances—Place 10.0 g of Microcrystalline Cellulose in a column having an internal diameter of about 20 mm, and pass 50 mL of peroxide-free diethyl ether through the column. Evaporate the eluate to dryness in a previously dried and tared evaporation dish. The difference between the mass of the residue and the mass obtained from a blank determination does not exceed 5.0 mg.

(3) Heavy metals—Proceed with 2.0 g of Microcrystalline Cellulose according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

	$[\eta]C$									
η_{rel}	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
6.1	2.447	2.450	2.453	2.456	2.458	2.461	2.464	2.467	2.470	2.472
6.2	2.475	2.478	2.481	2.483	2.486	2.489	2.492	2.494	2.497	2.500
6.3	2.503	2.505	2.508	2.511	2.513	2.516	2.518	2.521	2.524	2.526
6.4	2.529	2.532	2.534	2.537	2.540	2.542	2.545	2.547	2.550	2.553
6.5	2.555	2.558	2.561	2.563	2.566	2.568	2.571	2.574	2.576	2.579
6.6	2.581	2.584	2.587	2.590	2.592	2.595	2.597	2.600	2.603	2.605
6.7	2.608	2.610	2.613	2.615	2.618	2.620	2.623	2.625	2.627	2.630
6.8	2.633	2.635	2.637	2.640	2.643	2.645	2.648	2.650	2.653	2.655
6.9	2.658	2.660	2.663	2.665	2.668	2.670	2.673	2.675	2.678	2.680
7.0	2.683	2.685	2.687	2.690	2.693	2.695	2.698	2.700	2.702	2.705
7.1	2.707	2.710	2.712	2.714	2.717	2.719	2.721	2.724	2.726	2.729
7.2	2.731	2.733	2.736	2.738	2.740	2.743	2.745	2.748	2.750	2.752
7.3	2.755	2.757	2.760	2.762	2.764	2.767	2.769	2.771	2.774	2.776
7.4	2.779	2.781	2.783	2.786	2.788	2.790	2.793	2.795	2.798	2.800
7.5	2.802	2.805	2.807	2.809	2.812	2.814	2.816	2.819	2.821	2.823
7.6	2.826	2.828	2.830	2.833	2.835	2.837	2.840	2.842	2.844	2.847
7.7	2.849	2.851	2.854	2.856	2.858	2.860	2.863	2.865	2.868	2.870
7.8	2.873	2.875	2.877	2.879	2.881	2.884	2.887	2.889	2.891	2.893
7.9	2.895	2.898	2.900	2.902	2.905	2.907	2.909	2.911	2.913	2.915
8.0	2.918	2.920	2.922	2.924	2.926	2.928	2.931	2.933	2.935	2.937
8.1	2.939	2.942	2.944	2.946	2.948	2.950	2.952	2.955	2.957	2.959
8.2	2.961	2.963	2.966	2.968	2.970	2.972	2.974	2.976	2.979	2.981
8.3	2.983	2.985	2.987	2.990	2.992	2.994	2.996	2.998	3.000	3.002
8.4	3.004	3.006	3.008	3.010	3.012	3.015	3.017	3.019	3.021	3.023
8.5	3.025	3.027	3.029	3.031	3.033	3.035	3.037	3.040	3.042	3.044
8.6	3.046	3.048	3.050	3.052	3.054	3.056	3.058	3.060	3.062	3.064
8.7	3.067	3.069	3.071	3.073	3.075	3.077	3.079	3.081	3.083	3.085
8.8	3.087	3.089	3.092	3.094	3.096	3.098	3.100	3.102	3.104	3.106
8.9	3.108	3.110	3.112	3.114	3.116	3.118	3.120	3.122	3.124	3.126
9.0	3.128	3.130	3.132	3.134	3.136	3.138	3.140	3.142	3.144	3.146
9.1	3.148	3.150	3.152	3.154	3.156	3.158	3.160	3.162	3.164	3.166
9.2	3.168	3.170	3.172	3.174	3.176	3.178	3.180	3.182	3.184	3.186
9.3	3.188	3.190	3.192	3.194	3.196	3.198	3.200	3.202	3.204	3.206
9.4	3.208	3.210	3.212	3.214	3.215	3.217	3.219	3.221	3.223	3.225
9.5	3.227	3.229	3.231	3.233	3.235	3.237	3.239	3.241	3.242	3.244
9.6	3.246	3.248	3.250	3.252	3.254	3.256	3.258	3.260	3.262	3.264
9.7	3.266	3.268	3.269	3.271	3.273	3.275	3.277	3.279	3.281	3.283
9.8	3.285	3.287	3.289	3.291	3.293	3.295	3.297	3.298	3.300	3.302
9.9	3.304	3.305	3.307	3.309	3.311	3.313	3.316	3.318	3.320	3.321

	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
10	3.32	3.34	3.36	3.37	3.39	3.41	3.43	3.45	3.46	3.48
11	3.50	3.52	3.53	3.55	3.56	3.58	3.60	3.61	3.63	3.64
12	3.66	3.68	3.69	3.71	3.72	3.74	3.76	3.77	3.79	3.80
13	3.80	3.83	3.85	3.86	3.88	3.89	3.90	3.92	3.93	3.95
14	3.96	3.97	3.99	4.00	4.02	4.03	4.04	4.06	4.07	4.09
15	4.10	4.11	4.13	4.14	4.15	4.17	4.18	4.19	4.20	4.22
16	4.23	4.24	4.25	4.27	4.28	4.29	4.30	4.31	4.33	4.34
17	4.35	4.36	4.37	4.38	4.39	4.41	4.42	4.43	4.44	4.45
18	4.46	4.47	4.48	4.49	4.50	4.52	4.53	4.54	4.55	4.56
19	4.57	4.58	4.59	4.60	4.61	4.62	4.63	4.64	4.65	4.66

Conductivity (i) Potassium chloride conductivity calibration standard solution—Weigh exactly 0.744 g of powdered potassium chloride, previously dried at 500–600°C for 4 hours, and dissolve in water at 20 ± 0.1°C to make exactly 1000 mL. To exactly 100 mL of this solution add water at 20 ± 0.1°C to make exactly 1000 mL. The conductivity constant of this solution, χ_{KCl}, at 25°C is 146.9 $\mu S \cdot cm^{-1}$.

(ii) Apparatus—Use an appropriate conductivity meter having the cell constant of between 0.01 and 0.1 cm^{-1}. Usually, the conductivity meter consists of a detector and indicator. The detector consists of a cell including electrodes in it. The cell with a temperature compensation circuit is preferable.

(iii) Procedure—Rinse 2 to 3 times the cell, previously washed well with water, with a potassium chloride conductivity calibration standard solution, fill up with the calibration standard solution, and determine the conductivity of the calibration standard solution kept at 25 ± 0.1°C. Repeat the determination, and measure the conductivity of the calibration standard solution, G_{χ_0} (μS), after a stable reading of ± 3% is obtained. The cell constant, J, is calculated by the following:

$$J = \frac{\chi_{KCl} + \chi_{H_2O}}{G_{\chi_0}}$$

J: cell constant (cm^{-1})

χ_{KCl}: conductivity constant of the potassium chloride conductivity calibration standard solution ($\mu S \cdot cm^{-1}$) (25°C)

χ_{H_2O}: conductivity constant of water used for preparation of the potassium chloride conductivity calibration standard solution ($\mu S \cdot cm^{-1}$)(25°C)

G_{χ_0}: conductivity measured (μS)

Use the supernatant obtained in the pH test as the sample solution. After washing well the cell with water, rinse the cell with the sample solution 2 to 3 times, fill up with the sample solution, and determine the conductivity of the sample solution, G_T (μS), kept at 25 ± 0.1°C. Determine the conductivity of water used for the preparation of the sample solution, G_0 (μS), in the same manner as above, and calculate the conductivity constants, χ_T ($\mu S \cdot cm^{-1}$) and χ_0 ($\mu S \cdot cm^{-1}$), by the following expressions: the value, $\chi_T - \chi_0$, is not more than 75 $\mu S \cdot cm^{-1}$.

$$\chi_T\ (\mu S \cdot cm^{-1}) = JG_T$$
$$\chi_0\ (\mu S \cdot cm^{-1}) = JG_0$$

Loss on drying Not more than 7.0% and within a range as specified on the label (1 g, 105°C. 3 hours).

Residue on ignition Not more than 0.05% (2 g).

Bulk density Put a No.10 sieve (1700 μm) at a position of about 20 cm above a tared brass or stainless steel cup, which has a capacity of 25.0 ± 0.05 mL and an inside diameter of 30.0 ± 2.0 mm, and slowly pour Microcrystalline Cellulose through the sieve, at a rate suitable to prevent clogging, until the cup overflows. Level the excess powder with the aid of a slide glass, weigh the filled cup, and weigh accurately the content of the cup, and then calculate the bulk density by the following expression: the bulk density is within the labeled specification.

$$\text{Bulk density } (g/cm^3) = \frac{A}{25}$$

A: measured mass of the content of the cup (g)

Microbial limits The total aerobic microbial count is not more than 1000 per g, the total count of fungi and yeast is not more than 100 per g, and yeast is not more than 100 per g, and *Escherichia coli, Salmonella, Pseudomonas aeruginosa* and *Staphylococcus aureus* should not be observed.

Containers and storage Containers—Tight containers.

Powdered Cellulose

粉末セルロース

Powdered Cellulose is a purified, mechanically disintegrated alpha cellulose obtained as a pulp, after partial hydrolysis as occasion demands, from fibrous plant materials.

The label indicates the mean degree of polymerization value with a range.

Description Powdered Cellulose occurs as a white powder.

It is practically insoluble in water, in ethanol (95) and in diethyl ether.

Identification **(1)** Dissolve 20 g of zinc chloride and 6.5 g of potassium iodide in 10.5 mL of water, add 0.5 g of iodine, and shake for 15 minutes. Place about 10 mg of Powdered Cellulose on a watch glass, and disperse in 2 mL of this solution: the substance develops a blue-violet color.

(2) Mix 30 g of Powdered Cellulose with 270 mL of water in a high-speed (18,000 revolutions per minute or more) blender for 5 minutes, transfer 100 mL of the dispersion to a 100-mL graduated cylinder, and allow to stand for 1 hour: a supernatant liquid appears above the layer of the cellulose.

(3) Transfer 0.25 g of Powdered Cellulose, accurately weighed, to a 125-mL conical flask, add exactly 25 mL each of water and 1 mol/L cupriethylenediamine TS, and proceed as directed in the Identification (3) under Microcrystalline Cellulose, beginning with "Immediately purge the solution with nitrogen". The mean degree of polymerization, p, is between 440 and 2250 and is within the labeled specification.

pH Mix 10 g of Powdered Cellulose with 90 mL of recently boiled and cooled water, and allow to stand for 1 hour with occasional stirring: the pH of the supernatant liquid is between 5.0 and 7.5.

Purity **(1)** Water-soluble substances—Mix 6.0 g of Powdered Cellulose with 90 mL of recently boiled and cooled water, and allow to stand for 10 minutes with occasional stirring. Filter, with the aid of vacuum, discard the first 10 mL of the filtrate, and pass the subsequent filtrate through the same filter, if necessary, to obtain a clear filtrate. Evaporate a 15.0-mL portion of the filtrate in a tared evaporating dish to dryness without charring, dry at 105°C for 1 hour, and weigh: the difference between the mass of the residue and the mass obtained from a blank determination does not exceed 15.0 mg.

(2) Diethyl ether-soluble substances—Place 10.0 g of Powdered Cellulose in a column having an internal diameter of about 20 mm, and pass 50 mL of peroxide-free diethyl ether through the column. Evaporate the eluate to dryness in