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

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 15.0 mg.

(3) Heavy metals—Proceed with 2.0 g of Powdered 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).

Loss on drying Not more than 6.0% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.3% (1 g calculated on the dried basis, the addition of sulfuric acid being omitted from the procedure).

Microbial limits The total aerobic microbial count does not exceed 1000 per g, the total combined fungus and yeast count does not exceed 100 per g, and *Escherichia coli, Salmonella* species, *Staphylococcus aureus* and *Pseudomonas aeruginosa* are not observed.

Containers and storage Containers—Tight containers.

Cellulose Acetate Phthalate

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Cellulose acetate benzene-1,2-dicarboxylate
[*9004-38-0*]

Cellulose Acetate Phthalate is a reaction product of phthalic anhydride and partially acetylated cellulose.

Cellulose Acetate Phthalate, calculated on the anhydrous and free acid-free basis, contains not less than 21.5% and not more than 26.0% of acetyl group ($-COCH_3$: 43.05), and not less than 30.0% and not more than 40.0% of carboxybenzoyl group ($-COC_6H_4COOH$: 149.13).

Description Cellulose Acetate Phthalate occurs as a white powder or grain. It is odorless or has a faint, acetous odor.

It is freely soluble in acetone, and practically insoluble in water, in methanol, in ethanol (95) and in dichloromethane.

Identification (1) Determine the infrared absorption spectrum of Cellulose Acetate Phthalate as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or spectrum of Cellulose Acetate Phthalate Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) Dissolve 150 mg of Cellulose Acetate Phthalate in 1 mL of acetone, and pour on a surface of a transparent glass plate in a well-ventilated place: a lustrous transparent film is formed after evaporating of the acetone.

Viscosity Weigh accurately a quantity of Cellulose Acetate Phthalate, equivalent to 15 g calculated on the anhydrous basis, dissolve in 85 g of a mixture of acetone and water (249: 1 in mass), and perform the test with this solution at 25 ± 0.2°C as directed in Method 1 under the Viscosity Determination to obtain the kinematic viscosity v. Separately, determine the density, ρ, of Cellulose Acetate Phthalate as directel under the Determination of Specific Grevity and Density, and calculate the viscosiy, η, as $\eta = \rho v$: not less than 45 mPa·s and not more than 90 mPa·s.

Purity (1) Heavy metals—Proceed with 2.0 g of Cellulose Acetate Phthalate 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).

(2) Free acids—Weigh accurately about 3.0 g of Cellulose Acetate Phthalate, put in a glass-stoppered conical flask, add 100 mL of diluted methanol (1 in 2), stopper tightly, and filter after shaking for 2 hours. Wash both the flask and residue with two 10-mL portions each of diluted methanol (1 in 2), combine the washes to the filtrate, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform the blank determination with 120 mL of diluted methanol (1 in 2), and make any necessary correction.

$$\text{Amount (\%) of free acids} = \frac{0.8306 \times A}{W}$$

A: amount (mL) of 0.1 mol/L sodium hydroxide consumed
W: amount (g) of the test sample, calculated on the anhydrous basis

The amount of free acids is not more than 3.0%, calculated as phthalic acid ($C_8H_6O_4$: 166.13).

Water Not more than 5.0% (1 g, direct titration, using a mixture of dehydrated methanol and dichloromethane (3:2) instead of methanol for Karl Fischer method).

Residue on ignition Not more than 0.1% (1 g).

Assay (1) Carboxybenzoyl group—Weigh accurately about 1 g of Cellulose Acetate Phthalate, dissolve in 50 mL of a mixture of ethanol (95) and acetone (3: 2), and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS). Perform a blank determination, and make any necessary correction.

$$\text{Content (\%) of carboxybenzoyl group } (C_8H_5O_3) = \frac{\dfrac{1.491 \times A}{W} - 1.795 \times B}{100 - B} \times 100$$

A: amount (mL) of 0.1 mol/L sodium hydroxide consumed
B: amount (%) of free acids obtained in Purity (2) Free acids
W: amount (g) of the test sample, calculated on the anhydrous basis

(2) Acetyl group—Weigh accurately about 500 mg of Cellulose Acetate Phthalate, put in a glass-stoppered conical flask, add 50 mL of water and exactly 50 mL of 0.5 mol/L sodium hydroxide VS, and boil for 60 minutes under a reflux condenser. After cooling, add 5 drops of phenolphthalein TS, and titrate with 0.5 mol/L hydrochloric acid VS. Perform a blank determination, and make any necessary correction.

$$\text{Content (\%) of free acids and bound acetyl group } (C_2H_3O) = \frac{2.152 \times A}{W}$$