

Methylcellulose

メチルセルロース

Methylcellulose is a methyl ether of cellulose. It, when dried, contains not less than 26.0% and not more than 33.0% of methoxyl group ($-\text{OCH}_3$: 31.03).

The kinematic viscosity of Methylcellulose is shown in square millimeter (mm^2/s) on the label.

Description Methylcellulose occurs as a white to yellowish white, powder or granules. It is odorless, or has a faint, characteristic odor, and is tasteless.

It is practically insoluble in ethanol (99.5), in acetone and in diethyl ether.

Methylcellulose swells, when water is added, and forms a clear or slightly turbid, viscous liquid.

Identification (1) To 1 g of Methylcellulose add 100 mL of hot water, cool to room temperature with stirring, and use this solution as the sample solution. Add anthrone TS gently to 5 mL of the sample solution: a blue to blue-green color is produced at the zone of contact.

(2) To 0.1 mL of the sample solution obtained in (1) add 9 mL of diluted sulfuric acid (9 in 10), shake, heat in a water bath for exactly 3 minutes, immediately cool in an ice bath, add carefully 0.6 mL of ninhydrin TS, shake, and allow to stand at 25°C: a red color develops immediately, and it does not change to purple within 100 minutes.

(3) Take 5 mg of Methylcellulose in a small test tube, add 2 drops of a solution of 25% hydrated benzoyl peroxide in acetone (1 in 10), evaporate on a water bath to dryness, fix a glass rod wetted with disodium chlomotropate TS at the lower end, into the small test tube with a cork stopper, and heat in a bath at 125°C for 5 to 6 minutes: the disodium chlomotropate TS shows a red-purple color.

(4) Heat the sample solution obtained in (1) in a water bath: a white turbidity or precipitate, which disappears upon cooling, is produced.

Viscosity Weigh exactly an amount of Methylcellulose, equivalent to 2.000 g, calculated on the dried basis, add 98 mL of water previously heated to 85°C, and stir by mechanical means for 10 minutes. Continue the stirring for another 40 minutes in an ice bath until dissolution is complete, add water to make 100.0 g, and if necessary centrifuge the solution to expel any entrapped air bubble. Determine the viscosity according to Method 1 under the Viscosity at 20°C: the viscosity of Methylcellulose is not less than 80% and not more than 120% of the labeled unit.

pH To 1.0 g of Methylcellulose add 100 mL of hot water, shake to suspend, and cool: the pH of this solution is between 5.0 and 8.0.

Purity (1) Clarity of solution—Add 20 mL of hot water to 0.5 g of Methylcellulose, disperse with thorough stirring, while heating on a water bath, and cool to 5°C. After cooling, add water to make 50 mL, transfer to a Nessler tube, and observe the turbidity from the side of the tube: the solution has no more turbidity than the following control solution.

Control solution: To 2.0 mL of 0.005 mol/L sulfuric acid VS add 1 mL of dilute hydrochloric acid, 45 mL of water and

2 mL of barium chloride TS, mix, and allow to stand for 10 minutes. Shake this solution before use.

(2) Chloride—Add 30 mL of hot water to 1.0 g of Methylcellulose, stir well, heat on a water bath for 10 minutes, filter by decantation, while hot, wash the residue well with hot water, and combine the washings with the above-mentioned filtrate. After cooling, add water to make 100 mL. Take 5 mL of this solution, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.284%).

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

(4) Iron—Prepare the test solution with 0.20 g of Methylcellulose according to Method 3, and perform the test according to Method A. Prepare the control solution with 2.0 mL of Standard Iron Solution (not more than 100 ppm).

(5) Arsenic—Prepare the test solution with 1.0 g of Methylcellulose according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 5.0% (1 g, 105°C, 1 hour).

Residue on ignition Not more than 1.0% (1 g).

Assay Weigh accurately about 0.025 g of Methylcellulose, previously dried, then proceed as directed under the Methoxyl Determination, and perform the assay.

Containers and storage Containers—Well-closed containers.

Morphine and Atropine Injection

モルヒネ・アトロピン注射液

Morphine and Atropine Injection is an aqueous solution for injection.

It contains not less than 0.91 w/v% and not more than 1.09 w/v% of morphine hydrochloride ($\text{C}_{17}\text{H}_{19}\text{NO}_3 \cdot \text{HCl} \cdot 3\text{H}_2\text{O}$: 375.84), and not less than 0.027 w/v% and not more than 0.033 w/v% of atropine sulfate [$(\text{C}_{17}\text{H}_{23}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4 \cdot \text{H}_2\text{O}$: 694.83].

Method of preparation

Morphine Hydrochloride	10 g
Atropine Sulfate	0.3 g
Water for Injection	a significant quantity
To make 1000 mL	

Prepare as directed under Injections, with the above ingredients.

Description Morphine and Atropine Injection is a clear, colorless liquid.

It is affected by light.

pH: 2.5 – 5.0

Identification (1) To 1 mL of Morphine and Atropine Injection add 1 mL of ethanol (99.5), mix, and use this solution