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Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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Specifications of Dimethyl-β-cyclodextrin

1. Description

Dimethyl-β-cyclodextrin occurs as white to pale yellow crystalline powder.

Melting point: Not less than 300°C (decomposition)

Dimethyl-β-cyclodextrin is tested according to the Melting Point Determination specified in General tests, Japanese Pharmacopeia.

2. Identification

- 1) Dissolve 1 g of dimethyl-β-cyclodextrin in 10 mL of water and use this solution as sample solution. When 1 mL of anthrone test solution is added to 2 mL of the sample solution carefully: blue to green is produced at their interface.
- 2) When sample solution containing 1 g of dimethyl-β-cyclodextrin in 10 mL of water is heated on water bath, the solution becomes turbid or produces white precipitate. When this solution is cooled, turbidity or white precipitate is dissolved.

3. Optical rotation

$[\alpha]_D^{20}$: +158 - 170° (after drying, 1 g, water, 100 mL, 100 mm)

Dimethyl-β-cyclodextrin is tested according to Optical Rotation Determination specified in General tests, Japanese Pharmacopeia.

4. Purity

1) Clarity and color of solution

Dissolve 1.0 g of dimethyl-β-cyclodextrin in 5 mL of water, the solution is clear and colorless. Measure the absorbance at 550 nm. Verify that the absorbance is not more than 0.020.

2) Heavy metals

Proceed with 2.0 g of dimethyl-β-cyclodextrin according to Method 2, Heavy Metal test specified in General tests, Japanese Pharmacopeia, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm). If test solution exhibits yellow of less intensity compared to the control solution, it meets the requirement of test.

3) Related substances

Add water to 1 g of dimethyl-β-cyclodextrin to make 5mL solution and dissolve it, and use this solution as sample solution. Pipet 1 mL of the sample solution, add water to make 10 mL solution, and use this solution as standard solution. Using these solutions, dimethyl-β-cyclodextrin is tested

according to thin-layer chromatography specified in General tests, Japanese Pharmacopeia. Spot each 1 μ L aliquots of sample solution and standard solution on a plate of silica gel for Thin-layer Chromatography. Develop the plate with a mixture of Chloroform and ethanol (9:1) to distance about 10 cm as developing solvent, and air-dry the plate. Spray evenly the plate with a solution of phosphomolybdic acid in ethanol (1 in 5), and heat at 105°C for 10 seconds: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

4) Thermal stability

When 1.0g of dimethyl- β -cyclodextrin is heated, sample is not colorized after heated at 80°C for 72 hours.

5) Arsenic

Not more than 2 ppm (1.0 g).

Proceed with 1.0 g of dimethyl- β -cyclodextrin according to Method 1, Arsenic test specified in General tests, Japanese Phamacopeia, and perform the test using apparatus B.

5. Loss on drying

Not more than 2.0% (1 g, 80°C, 72 hours)

Dimethyl- β -cyclodextrin is tested according to the Loss on Drying Test specified in General tests, Japanese Pharmacopeia.

6. Residue on ignition

Not more than 0.1% (1 g)

Dimethyl- β -cyclodextrin is tested according to the Residue on Ignition Test specified in General tests, Japanese Pharmacopeia.