mL of water, warm in a water bath for 5 minutes with occasional shaking, and filter. Cool the filtrate, and add 2 to 3 drops of gelatin TS: a white turbidity or precipitate is produced.

(2) Shake 0.1 g of Powdered Gambir with 20 mL of dilute ethanol for 2 minutes, and filter. Mix 1 mL of the filtrate with 9 mL of dilute ethanol, and to the solution add 1 mL of vanillin-hydrochloric acid TS: a light red to red-brown color develops.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.5%.

Extract content Dilute ethanol-soluble extract: not less than 70.0%.

β-Galactosidase (Aspergillus)

Aspergillus Galactosidase

β-ガラクトシダーゼ(アスペルギルス)

[*9031-11-2*]

β-Galactosidase (Aspergillus) contains an enzyme produced by *Aspergillus oryzae*. It is an enzyme drug having lactose decomposition activity, and contains 8000 to 12000 units per g. Usually, it is diluted with a mixture of maltose and dextrin, maltose and D-mannitol, or maltose, dextrin and D-mannitol.

Description β-Galactosidase (Aspergillus) occurs as a white to light yellow powder.

It is slightly soluble in water with a turbidity, and practically insoluble in ethanol (95) and in diethyl ether.

Identification (1) Dissolve 0.025 g of β-Galactosidase (Aspergillus) in 100 mL of water, then to 1 mL of this solution add 9 mL of lactose substrate TS, and stand at 30°C for 10 minutes. To 1 mL of this solution add 6 mL of glucose detection TS, and stand at 30°C for 10 minutes: a red to red-purple color develops.

(2) Dissolve 0.1 g of β-Galactosidase (Asperigillus) in 100 mL of water, and filter the solution if necessary. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

Purity (1) Odor—β-Galactosidase (Aspergillus) has no any rancid odor.

(2) Heavy metals—Proceed with 1.0 g of β-Galactosidase (Aspergillus) according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

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

Loss on drying Not more than 9.0% (0.5 g, in vacuum, 80°C, 4 hours).

Residue on ignition Not more than 3.0% (0.5 g).

Nitrogen content Weigh accurately about 0.07 g of β-Galactosidase (Aspergillus), and perform the test as directed under the Nitrogen Determination: the amount of nitrogen (N: 14.007) is between 0.5% and 5.0%, calculated on the dried basis.

Assay (i) Substrate solution: Dissolve 0.172 g of 2-nitrophenyl-β-D-galactopyranoside in disodium hydrogenphosphate-citric acid buffer solution, pH 4.5 to make 100 mL.

(ii) Procedure: Weigh accurately about 0.025 g of β-Galactosidase (Aspergillus), dissolve in water to make exactly 100 mL, then pipet 2 mL of this solution, add water to make exactly 50 mL, and use this solution as the sample solution. Take exactly 3.5 mL of the substrate solution, stand at 30 ± 0.1°C for 5 minutes, add exactly 0.5 mL of the sample solution, immediately mix, and stand at 30 ± 0.1°C for exactly 10 minutes, then add exactly 1 mL of sodium carbonate TS and mix immediately. Determine the absorbance, A_1, of this solution at 420 nm using water as the control. Separately, take exactly 3.5 mL of the substrate solution, add exactly 1 mL of sodium carbonate TS and mix, then add exactly 0.5 mL of the sample solution and mix. Determine the absorbance, A_2, of this solution in the same manner as above.

$$\text{Units per g of β-Galactosidase (Aspergillus)} = \frac{A_1 - A_2}{0.917} \times \frac{1}{0.5} \times \frac{1}{10} \times \frac{1}{W}$$

0.917: Absorbance of 1 μmol/ 5 mL of *o*-nitrophenol

W: Amount (g) of the sample in the sample solution per mL

Unit: One unit indicates an amount of the enzyme which decomposes 1 μmol of 2-nitrophenyl-β-D-galactopyranoside in 1 minute under the above conditions.

Containers and storage Containers—Tight containers.

Storage—In a cold place.

β-Galactosidase (Penicillium)

β-ガラクトシダーゼ(ペニシリウム)

[*9031-11-2*]

β-Galactosidase (Penicillium) contains an enzyme, having lactose decomposition activity, produced by *Penicillium multicolor*. It contains not less than 8500 units and not more than 11,500 units in each g. Usually, it is diluted with D-mannitol.

Description β-Galactosidase (Penicillium) occurs as a white to pale yellowish white, crystalline powder or powder.

It is soluble in water with a turbidity, and practically insoluble in ethanol (95).

It is hygroscopic.

Identification (1) Dissolve 0.05 g of β-Galactosidase (Penicillium) in 100 mL of water, then to 0.2 mL of this solution add 0.2 mL of lactose substrate TS, and allow to stand at 30°C for 10 minutes. To this solution add 3 mL of glucose detection TS, and allow to stand at 30°C for 10 minutes: a red to red-purple color develops.