L Histidine Monohydrochloride Monohydrate

Specifications for feed additives

Raw material for manufacturing

Compositional specifications

Content: When this product is determined following a 3-hour drying at 105℃, it contains more than 98.0% of L Histidine Monohydrochloride Monohydrate ($C_6H_9N_3O_2 \cdot HCl \cdot H_2O$)

Physical and chemical properties

(1) It appears white crystals or crystalline powder.

(2) The pH of this solution or suspension (1 in 10) in water is between 3.5 and 4.5.

Confirmation test:

(1) 5mL of a solution of this (1 in 1,000) add into 5ml of Ninhydrin solution (1 in 1,000), and heat for 3 minutes: a purple color develops.

(2) A solution of this (1 in 10) reacts to qualitative test of Chloride.

Purity test:

(1) Specific rotation: Weigh about 5.5g of this to digit of 0.01g, and calculate the record converted as dry matter, and then dissolve it in 6mol/L Hydrochloric acid solution to make 50mL, and filter if necessary: the Specific Rotation $[\alpha]^{20}D$ of this solution must be between +8.5° and +10.5°.

(2) Lead: Weigh 5.0g (4.95 to 5.04g) of this and perform the test for lead as directed in the Lead Test (Atomic Absorption Spectrophotometry Method 1); the amount of lead must be not more than 2μg/g. Pipet 1.0mL of Standard Lead Solution and add nitric acid (1 in 150) to make exactly 10mL and use this solution as the standard solution.

(3) Arsenic: Place 1.0g (0.95 to 1.04g) of this in a decomposition flask, add 10 mL of Nitric acid and 5mL of Sulfuric acid, and heat gently. If the solution is brown in color, allow to cool, add 1 to 2mL of Nitric acid, heat, and repeat this procedure until the solution is colorless to pale yellow. After cooling, add 0.5mL of Perchloric acid, and heat until white fumes are evolved. After cooling, add 15mL of a saturated solution of Ammonium oxalate, and heat until white fumes are evolved again. After cooling, add water to make about 10mL, and use this solution as the sample solution. Perform the test with the sample solution according to the method with Apparatus A. Observe the color of the absorbing solution: the color produced must not be more intense than the standard color (not more than 2μg/g).

(4) Ammonium salt: The purity test iii. for the raw material for manufacturing of aminoacetic acid is applied mutatis mutandis. In this case, "0.1 g" shall be read as "0.05 g" and "1 mL" shall be read as "0.5 mL"(not more than 0.04 %).

Loss on drying: ≤ 0.3 % (3 g, 105℃, 3 hours)

Ignition residue: ≤ 0.1 % (1 g)

Assay: Dry this at 105°C for 3 hours and weigh about 0.5g of this to digit of 0.1mg, record its weigh, add water to dissolve and pour into 1,000mL measuring flask and add water to make 1,000mL. Use this solution as the sample solution.

Perform the test with 5µl of the sample solution as directed under Liquid Chromatography according to the following conditions. Determine the peak area of Histidine in the chromatogram, calculate the concentration of L-Histidine Monohydrochloride Monohydrate based on the calibration curve separately determined, and calculate the content.

Operating conditions

Detector: A ultraviolet absorptiometer (mensural wavelength of 210 nm)

Column: A stainless steel column 4.6mm in inside diameter and 150mm in length, packed with Octadecylsilylated silica gel for Liquid Chromatography (3µm in particle diameter).

Column temperature: 35°C

Mobile phase: Dissolve 2.27g (2.265 to 2.274g) of Potassium dihydrogen phosphate and 1.08g (1.075 to 1.084g) of Sodium 1-Octane sulfonate in 850mL of water. After adjusting the pH to 2.5 with Phosphoric acid, add 100mL of Acetonitrile and mix and then add water to make 1,000mL of solution.

Flow rate: 1.0mL per minute

Creation of calibration curve

Weigh about 0.05g, 0.1g, 0.5g and 1g of L-Histidine chloride for assay to the digit of 0.1mg respectively and record their weight, add about 800mL of water to dissolve and pour into 1,000mL measuring flask and add water to make 1,000mL. Use these solutions as the standard stock solution. (1mL of the solution contains 0.05mg, 0.1mg, 0.5mg or 1mg, respectively.)

Perform the test with 5µL each of the standard solution as directed under Liquid Chromatography in the same manner as the sample solution. Determine the peak area of L-Histidine in the Chromatogram and prepare a calibration curve.

Standards for manufacturing methods:

Culture *Corynebacterium glutamicum* strain for Histidine production aerobically, filter the culture broth to remove bacteria after completion of the culture, and isolate the crude L-Histidine crystal fraction. Furthermore, purity the crude crystals and dry the solid substances obtained.

Standards for storage methods:

Store in a well-closed container.

Preparation

Compositional specifications

Apply the compositional specifications of L-Histidine raw material for manufacturing.

Standards for storage methods

Apply the standards for storage methods of L-Histidine raw material for manufacturing.