NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB 1886.353-2021

National Food Safety Standard - Food Additive - gamma-cyclodextrin

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Issued by: National Health Commission;
State Administration for Market Regulation

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1 Scope

This Standard applies to the food additive gamma-cyclodextrin that is prepared by enzymatic hydrolysis and extraction of starch.

2.1 Molecular formula

(C6H10O5)8

2.2 Relative molecular mass

1297.13 (according to the international relative atomic mass in 2018)

3.1 Sensory requirements

Sensory requirements shall meet the requirements of Table 1.

3.2 Physical and chemical indicators

Physical and chemical indicators shall meet the requirements of Table 2.

Appendix A Inspection method

A.1 General provisions The reagents and water used in this Standard refer to analytical reagents and grade-3 water in accordance with GB/T 6682, when other requirements are not indicated. The standard solutions used in the test, the standard solutions for impurity determination, the preparations and products, unless otherwise specified, shall be prepared in accordance with GB/T 601, GB/T 602 and GB/T 603. The solution used in the test refers to an aqueous solution, when it is not specified which solvent is used to prepare it.

A.2 Identification test A.2.1 Specific rotation test Weigh 1.00 g of the sample and dissolve it in 100 mL of water; measure it according to the method that is specified in GB/T 613. The specific rotation shall be +173° ~ +180°.

A.2.2 Chromatographic test In the gamma-cyclodextrin content determination test, the

retention time of the main peak of the test solution chromatogram shall be consistent with the retention time of the main peak of the standard solution chromatogram.

A.3 Determination of gamma-cyclodextrin content (on a dry basis)

A.3.1 Reagents and materials A.3.1.1 Methanol: chromatographically pure.

A.3.1.2 Water: Grade-1 water specified in GB/T 6682.

A.3.1.3 gamma-cyclodextrin standard substance: purity >=98.0%.

A.3.2 Instruments and equipment High performance liquid chromatograph: equipped with a refractive index detector.

A.3.3 Reference chromatographic conditions A.3.3.1 Chromatographic column: C18, C8, phenyl column or other reverse chromatographic columns (5 um, 150 mm x 4.6 mm).

A.3.3.2 Mobile phase: water: methanol = 93: 7, if necessary, it can be adjusted.

A.3.3.3 Column temperature: 30 °C.

A.3.3.4 Detector temperature: 40 °C.

A.3.3.5 Flow rate: 1.0 mL/min.

A.3.3.6 Injection volume: 20 uL.

A.3.4 Analysis steps A.3.4.1 Preparation of standard solution Accurately weigh an appropriate amount of gamma-cyclodextrin standard product (on a dry basis, refer to Method 1 in GB 5009.3-2016 for the drying method); add water to dissolve; dilute to a standard solution of a concentration of about 1.0 mg/mL (on a dry basis). Use a 0.45 um microporous membrane for filtration before chromatographic analysis.

A.3.4.2 Preparation of analytical stock solution Accurately weigh 250 mg of the sample (on a dry basis, refer to Method 1 in

GB 5009.3-2016 for the drying method); put it in a 25 mL measuring flask; add water to dissolve it; take it out; let it cool; use water to dilute to the mark.

A.3.4.3 Preparation of analytical solution Precisely pipette 5.0 mL of analytical stock solution; place it in a 50.0 mL measuring flask; use water to dilute to the mark.

A.3.4.4 Preparation of system suitability solution Accurately weigh an appropriate amount of gamma-cyclodextrin standard substance (on a dry basis, refer to Method 1 in GB 5009.3-2016 for the drying method);

add water to dissolve; obtain a gamma-cyclodextrin solution of a concentration of about 0.5 mg/mL.

A.3.4.5 System suitability test Under the reference chromatographic conditions of A.3.3, respectively determine the standard solution and sample solution. The system suitability

means that, for 5 repeated injections of the standard solution, the relative standard deviation of the response area obtained is less than 2.0%.