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Lactulose

乳果糖

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Table of Contents

Lactulose

1 Scope

This standard specifies the product classification, requirements, test methods, inspection rules, marking, packaging, transportation, storage of lactulose.

This standard applies to lactulose, which is produced and processed using lactose as raw material, through isomerization, centrifugation, purification, concentration and other processes.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this standard.

GB/T 613 Chemical reagent - General method for the determination of specific optical rotatory power (specific optical rotation)

GB 2762 National food safety standard - Maximum levels of contaminants in foods

GB 5009.3-2010 National food safety standard - Determination of moisture content in foods

GB/T 6682-2008 Water for analytical laboratory use - Specification and test methods (ISO 3696:1987, MOD)

GB 7718 National food safety standard - Standard for nutrition labelling of prepackaged foods

GB 13509 Food additive - Xylitol

GB 14881 National food safety standard - General hygienic regulation for food production

GB 15203 Hygienic standard of corn sweetener

GB/T 20885 Glucose syrup

3 Chemical name, molecular formula, relative molecular

6.2.2 Moisture

Make determination, according to the method I of GB/T 5009.3-2010.

6.2.3 Burning residue

Make determination, according to the method specified in GB 13509.

6.2.4 Specific rotation

Make determination, according to the method specified in GB/T 613.

6.2.5 pH

Make determination, according to the method specified in GB/T 20885.

6.2.6 Melting point

Make determination, according to the method specified in GB 13509.

6.3 Contaminant limit

Make determination, according to the method specified in GB 2762.

6.4 Microbiological limits

The total number of bacterial colonies, coliforms, therapeutic bacteria are determined, according to the method specified in GB 15203.

6.5 Hygiene in production process

Make determination, according to the method specified in GB 14881.

7 Inspection rules

7.1 Group-batch

The products of same type and quality, which are produced by the same batch of materials, form a batch.

7.2 Sampling and sample retention

The samples are randomly taken from the finished product warehouse, from each batch based on output. The total sample shall not be less than 500 g.

7.3 Exit-factory inspection

The exit-factory inspection items are sense, lactulose content, moisture, burning residue,

total number of bacterial colonies, coliforms.

7.4 Type inspection

Type inspection items are all the items which are specified in this standard. In general, type inspection is once every 6 months. In one of the following conditions, type inspection shall also be carried out:

a) When the raw material and auxiliary material change significantly;

b) When the key process or equipment changes;

c) When the product is trial-produced OR when the production is restored after suspension of normal production for 3 months;

d) When the exit-factory inspection differs significantly from the results of last type inspection;

e) When the national quality supervisory inspection institute conducts spot checks, according to the relevant provisions.

7.5 Judgement rules

7.5.1 If all inspection items of the inspected sample are qualified, THEN, this batch of products are qualified.

7.5.2 When any one of the sensory requirements and physical-chemical indicators are unqualified, double the number of samples from this batch of products for re-inspection. The re-inspection result shall prevail.

7.5.3 When any one of the items of contaminant limit, microbial limit, production process is unqualified, THEN, this batch of products shall be unqualified.

8 Sign, packaging, transportation, storage

8.1 Sign

Prepackaging labels shall comply with the provisions of GB 7718.

8.2 Packaging

Packaging containers shall be clean AND comply with appropriate hygienic standards.

8.3 Transportation

During transportation, it shall be protected from exposure to the sun and rain. It is prohibited to transport it together with toxic and harmful substances.

Appendix A

(Normative)

Determination method of lactulose content

A.1 Summary of methods

Use high performance liquid chromatography. Under selected working conditions, use water as the mobile phase, to separate the components in the sample solution, through the chromatographic column. Use a differential refractive index detector, for detection. Use the external standard method or area method, for quantification. Calculate the lactulose content in the sample.

A.2 Reagents and materials

A.2.1 Water: GB/T 6682-2008, grade-1 water.

A.2.2 Lactulose standard: The purity shall be above 99.0%. Prepare 6 standard solution series, which have different concentrations (0.1 mg/mL, 0.2 mg/mL, 0.4 mg/mL, 0.8 mg/mL, 1.0 mg/mL, 2.0 mg/mL), in the range of 0.1 mg/mL ~ 10 mg/mL.

A.3 Instruments and equipment

A.3.1 High performance liquid chromatograph: It is equipped with a differential refractive index detector, or other equivalent detector.

A.3.2 Mobile phase vacuum filtration degassing device and 0.22 μm filter membrane.

A.3.3 Chromatographic column: A column (column size: Φ7.8 mm × 300 mm), which uses calcium-type strong acid positive ion exchange resin as filler, AND is dedicated for sugar or sugar alcohol analysis, or equivalent chromatographic column.

A.3.4 Analytical balance: The sensitivity is 0.1 mg.

A.3.5 Micro-sampler: 50 μL.

A.4 Reference chromatographic conditions

A.4.1 Mobile phase: GB/T 6682-2008, grade-1 water.

A.4.2 Column temperature: 80 °C.

A.4.3 Mobile phase flow rate: About 0.5 mL/min.

A.4.4 Sample injection volume: 20 μL.

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