



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 1903.15-2016

Replacing GB 15572-1995

Food additive -- Calcium acetate

食品安全国家标准 食品营养强化剂 醋酸钙（乙酸钙）

(English Translation)

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1 Scope

This standard applies to bromide, benzene acid, sodium salt as raw materials, chemical synthesis prepared food fortifier D- biotin.

2 Molecular formula, relative molecular mass and structural formula

Formula 2.1

C₁₀H₁₆N₂O₃S

2.3 Relative molecular mass

244.31 (according to 2007 international relative atomic mass)

3.1 Sensory requirements

Sensory requirements shall comply with the requirements of Table 1.

Table 1 Sensory requirements

Project requires test methods Color white or nearly white Status crystalline powder or crystal Take the right amount of sample is placed in a clean, dry colorless glass beaker , Under natural light, observe its color and status

3.2 Physical and Chemical Indicators

Physical and chemical indicators should be consistent with the provisions of Table 2.

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Table 2. Physical and chemical indicators

Item Index Test Method D- biotin content (dry basis), w /% 98.0 ~ 100.5 Appendix A A.3 Clarity through test A.4 in Appendix A Specific rotation α_D^{20} (20 °C, D)/[(°) · m² · kg⁻¹] 89 ~ 93 GB/T 613a Loss on drying, w /% ≤ 1.0 GB 5009.3 direct drying Residue on ignition, w /% ≤ 0.10 GB/T 9741 Lead (Pb)/(mg/kg) ≤ 2.0 GB 5009.75 or GB 5009.12 Arsenic (As)/(mg/kg) ≤ 1.0 GB 5009.76 a solvent 0.1mol/L sodium hydroxide solution, wherein the concentration of the effective component is 2%.

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Appendix A

Testing method

A.1 General Provisions Unless otherwise specified in this standard, the purity of the reagents used should be analytically pure, the standard titration solution, impurity measurement standard solution preparation and products, should be GB/T 601, GB/T 602, the provisions of the preparation of GB/T 603, the test water should be consistent with GB/T 6682 in the three water regulation set. Solution was used in the tests did not indicate what is formulated with solvent, it refers to an aqueous solution.

A.2 Identification Test A.2.1 infrared absorption spectrum test Using potassium bromide smear method, infrared absorption spectrum, measured infrared spectra should D- biotin control profile according to GB/T 6040 Consistent (control profile see Appendix B).

A.2.2 bromine water fade test Sample preparation saturated aqueous solution was added dropwise to the orange bromine, water fade.

Determination A.3 D- biotin content (dry basis) of A.3.1 Reagents and materials A.3.1.1 D- biotin standards. purity should be more than 99%.

A.3.1.2 acetonitrile. chromatography.

A.3.1.3 buffer solution. Weigh sodium perchlorate monohydrate 1g, dissolved into 500mL water, adding 1mL phosphoric acid, dilute to 1000mL.

A.3.1.4 Thinner. aqueous acetonitrile = 14.

A.3.2 Instruments and Equipment High performance liquid chromatograph. with UV detector (detection wavelength 200nm).

A.3.3 reference chromatographic conditions A.3.3.1 Column. 15cm x 4.6mm (diameter), particle size 3μm, ODS column or other equivalent column.

A.3.3.2 mobile phase. acetonitrile buffer = 8.5 91.5.

A.3.3.3 flow rate. 1.2mL/min.

A.3.3.4 Injection volume. 50μL.

NOTE: The system suitability is the tailing factor is not more than 1.5, and repeatedly injecting the

standard solution twice, resulting in response to the relative average area of less than 2.0% deviation.

A.3.4 Analysis step

A.3.4.1 Preparation of standard solutions Take appropriate standard solutions Standard D-Biotin dissolved in diluent, is configured to 0.1mg/mL, if necessary, ultrasonic treatment completely Dissolved.

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A.3.4.2 Preparation of sample solution Take appropriate samples D- biotin (via 105 °C, 4h dried) was dissolved in the diluent, the sample solution is configured to 0.1mg/mL, and if necessary Ultrasonic treatment completely dissolved.

A.3.4.3 Determination in reference chromatographic conditions, respectively, the standard solution and the sample solution were measured, recorded peak area, according to the formula (A.1) calculates the sample the D- biotin content.

A.3.5 Calculation Results D- biotin content (dry basis) of the mass fraction w_1 , according to equation (A.1) Calculated.

100% (A.1)

Where.

r_U --- sample liquid chromatographic peak area obtained;

r_S --- chromatographic analysis of standard solution peak area obtained;

c_S --- standard solution D- biotin concentration, in milligrams per milliliter (mg/mL);

The concentration of the sample solution c_U --- D- biotin, in milligrams per milliliter (mg/mL).

The results parallel arithmetic mean of the measurement results shall prevail.

A.4 Determination of Clarity 1.0g sample taken in 0.5mol/L sodium hydroxide solution, to dissolve the volume to 10.0mL, then the solution should be colorless and transparent.

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Appendix B

Standard infrared spectra D- biotin D- biotin standard infrared spectrum is shown in Figure B.1.

Note: quoted in force since April 1, 2011, "Japanese Pharmacopoeia (JP16)" --- InfraredReferenceSpectra.

Figure B.1 D- biotin standard infrared spectra