



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

GB 1903.25-2016

**National Food Safety Standard -- Food Nutritive Fortifier --
D-Biotin**

食品安全国家标准 食品营养强化剂 D-生物素

(English Translation)

Issued on: December 23, 2016

Implemented on: June 23, 2017

**Issued by: National Health and Family Planning Commission People's
Republic of China**

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1 Scope

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

2 Formula, Structure and molecular weight

Formula 2.1

C₁₀H₁₆N₂O₃S

2.3 Molecular Weight

244.31 (according to 2007 international relative atomic mass)

3.1 Sensory requirements

Sensory requirements shall comply with the requirements in Table 1.

Table 1 Sensory requirements

Project requires test methods Color white or nearly white State crystalline powder or crystal
Proper amount of sample is placed in a clean, dry glass beaker colorless , Under natural light, the color observed and the state

3.2 Physical and Chemical Indicators

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

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 Test by Appendix A A.4 Specific rotation α_D^{20} (20 °C, D)/[(°) · m² · kg⁻¹] 89 ~ 93

GB/T 613a Drying loss, w /% $\leq$ 1.0 GB 5009.3 direct drying Residue on ignition, w /% $\leq$ 0.10 GB/T 9741 Lead (Pb)/(mg/kg) $\leq$ 2.0 GB 5009.75 or GB 5009.12 Arsenic (As)/(mg/kg) $\leq$ 1.0 GB 5009.76 a solvent 0.1mol/L sodium hydroxide solution, wherein the concentration of the effective component is 2%.

Appendix A

Testing method

A.1 General Provisions Unless otherwise specified in this standard, it should be of analytical grade purity of the reagents, the titration standard solution, the determination of impurities with a standard solution, the formulation and products shall GB/T 601, GB/T 602, a predetermined preparation GB/T 603, the test water shall meet the GB/T 6682 in three water gauge set. The test does not indicate when the solution which is formulated with a solvent, refer to the aqueous solution.

A.2 Identification Test A.2.1 infrared absorption spectrum test Smear using potassium bromide, infrared absorption spectrum, the infrared spectrum to be measured and the control pattern in accordance with D- biotin GB/T 6040 Consistent (control profile see Appendix B).

A.2.2 bromine water fade test Saturated aqueous formulation samples was added dropwise to the orange bromine, water fade.

A.3 D- biotin in assay (dry basis) of A.3.1 Reagents and materials A.3.1.1 D- Biotin standard. Purity 99% or more.

A.3.1.2 Acetonitrile. chromatographically pure.

A.3.1.3 buffer solution. Weigh sodium perchlorate monohydrate 1g, was placed 500mL of water was dissolved, was added 1mL phosphoric acid, dilute to 1000mL.

A.3.1.4 diluent. water acetonitrile = 14.

A.3.2 Instruments and Equipment HPLC. with UV detector (detection wavelength of 200nm).

A.3.3 Reference chromatographic conditions A.3.3.1 Column. 15cm x 4.6mm (inside diameter), the filler particle size 3 μ m, ODS column, or other equivalent column.

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

A.3.3.3 flow rate. 1.2mL/min.

A.3.3.4 injection volume. 50 μ L.

NOTE: The system suitability tailing factor is not more than 1.5, and the standard solution is injected twice repeated, resulting in response to the relative deviation of the average area of less than 2.0%.

A.3.4 Analysis step

Preparation of standard solution A.3.4.1 Take appropriate standard D- biotin was dissolved in diluents, configured to 0.1mg/mL standard solution, if necessary, sonication completely Dissolved.

A.3.4.2 Preparation of test solution Take appropriate sample time D- biotin (via 105 °C, 4h drying treatment) was dissolved in diluents, configured to sample solution 0.1mg/mL, the necessary Sonication was completely dissolved.

A.3.4.3 Determination Under reference chromatographic conditions, the standard solutions were measured and the sample solution, the peak area of the recording, according to formula (A.1) the sample is calculated the content of D- biotin.

A.3.5 calculation results D- biotin content (dry basis) the mass fraction w_1 , calculated according to formula (A.1).

100% (A.1)

Where.

--- r_U sample liquid chromatographic analysis of the peak area obtained;

Chromatography of r_S --- standard solution obtained peak area;

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

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

The test result to the arithmetic mean of replicates results.

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

Appendix B

Standard IR spectra of the biotin-D-Standard IR spectra of D- biotin Figure B.1.

Note: The quote from "Japanese Pharmacopoeia (JP16)" --- InfraredReferenceSpectra 2011 Nian 4 Yue is effective 1 May.

FIG B.1 D- standard infrared spectra of biotin