

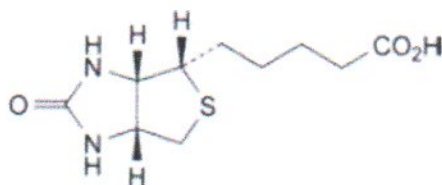
## SPECIFICATION

**Product:** BIOTIN , D-BIOTIN, (VITAMIN H)

**CAS NO.:** 58-85-5

**Structural formula:** C<sub>10</sub>H<sub>16</sub>N<sub>2</sub>O<sub>3</sub>S

**Structure:**



**Molecular weight:** 244.31

**Characters:** A white or almost white, crystalline powder or colourless crystals, very slightly soluble in water and in alcohol, practically insoluble in acetone. It dissolves in dilute solutions of alkali hydroxides.

### USP42

| Specifications               | Certified  | Test method |
|------------------------------|--|-------------|
| Identification A. IR         | To match with the reference IR spectrum  | USP<197K>   |
| B. Specific optical rotation | +89° to +93° (on dry material)   | USP<781S>   |
| C. HPLC                      | The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay | /           |
| Assay                        | 97.5%--102.0%  | HPLC        |
| Individual impurity          | NMT 1.0%   | HPLC        |
| Total impurities             | NMT 2.0%   | HPLC        |
| Lead                         | ≤3mg/kg  | USP<251>    |
| Arsenic                      | ≤1mg/kg  | USP<211>    |
| Cadmium                      | ≤1mg/kg  | USP<851>    |
| Mercury                      | ≤0.1mg/kg  | USP<261>    |

Add: No.789, Renmin East Road, Tiantai(317200), Zhejiang, China

Tel: +86-576-83881111 Fax: +86-576-83993731 Web: www.sd-pharm.com Email: export@sd-pharm.com

浙江圣达生物药业股份有限公司  
ZHEJIANG SHENGDA  
BIO-PHARM CO., LTD.

洪霞  
Authorised Signature

浙江圣达生物药业股份有限公司  
Zhejiang Shengda Bio-Pharm Co., Ltd.



|                   |            |           |
|-------------------|------------|-----------|
| Total plate count | ≤1000Cfu/g | USP<2021> |
| Yeast and Mold    | ≤100Cfu/g  | USP<2021> |
| E.Colinegative    | Negative   | USP<2022> |
| Salmonella        | Negative   | USP<2022> |

**Storage:** The shelf life is 36 months from the date of production when store protected from light at room temperature.

**Uses:** Food, Feed additives

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