



Product Specification

Ver_3.0_Issued in Apr, 2019

L – Leucine

1. Product and Company Information

White crystals or crystalline powder, Odorless, Slightly bitter taste, Freely soluble in formic acid, sparingly soluble in water

Chemical Formula : C₆H₁₃NO₂
 Formula Weight : 131.17 g/mol
 CAS Number : 61-90-5
 EINECS Number : 200-522-0
 Manufacturer Name : CJ Haide (Ningbo) Biotech Co., Ltd.
 Manufacturer Address : #799 Feng xiang Rd, Xiepu, Zhenhai, Ningbo 315204 China

2. Chemical / Analytical Information

This product meets quality requirements of USP41 monographs

| Analysis Item | Specification | Method |
|--|--|----------|
| Characters, Appearance | White or almost white, crystalline powder or colourless crystals | |
| Characters, Solubility | Freely soluble in formic acid, sparingly soluble in water | |
| Identification | Infrared absorption | USP 41 |
| Assay | NLT 98.5% and NMT 101.0% | USP 41 |
| Residue on Ignition (Sulfated Ash) | NMT 0.4% | USP 41 |
| Chloride | NMT 0.05% | USP 41 |
| Sulfate | NMT 0.03% | USP 41 |
| Ammonium | NMT 0.02% | In house |
| Iron | NMT 10 ppm | USP 41 |
| Lead | NMT 1 ppm | USP 41 |
| Arsenic | NMT 0.5 ppm | USP 41 |
| Cadmium | NMT 0.5 ppm | USP 41 |
| Mercury | NMT 0.1 ppm | USP 41 |
| Heavy Metals | NMT 10 ppm | USP 41 |
| Individual Impurities (Ninhydrin Positive) | NMT 0.5% | USP 41 |
| Total Impurities (Ninhydrin Positive) | NMT 2.0% | USP 41 |
| Optical Rotation | +14.9° to +17.3° (at 25°C) +14.5° to +16.5° (at 20°C) | USP 41 |
| pH | 5.5 ~ 7.0 | USP 41 |
| Loss on Drying | NMT 0.2% | USP 41 |

3. Microbiological Information

| Analysis Item | Specification | Method |
|-----------------------|----------------|--------|
| Total viable count | NMT 1000 cfu/g | USP 41 |
| Yeast & mould | NMT 100 cfu/g | USP 41 |
| Enterobacteriaceae | Negative/10g | ISO |
| Salmonella sp. | Negative/25g | USP 41 |
| Coliforms bacteria | Negative/g | USP 41 |
| Escherichia coli | Negative/g | USP 41 |
| Staphylococcus aureus | Negative/g | USP 41 |
| Bacillus sp. | Negative/g | GB |
| Clostridium sp. | Negative/g | USP 41 |

4. Storage Conditions & Shelf life

Keep container dry and tightly closed; Keep in a cool well-ventilated place; Keep away from heat and oxidizing agents.

Shelf life: Recommend usage within 3 years from date of production

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