# 3.2.S.6 Container Closure System

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**1) Type of Material**

L-Ornithine-L-Aspartate (LOA) isdouble packed in polyethylene bags (inner container) and fiber drums (External container). The polyethylene bag and fiber drum container system use are representative of the container system used to package finished L-Ornithine-L-Aspartate (LOA).

**2) Packing Methods**

The LOA uses a polyethylene bag as the primary packaging material to the tight Container. It is wrapped in a fiber-drum which is resistant to external impact by secondary packaging. It is packaged in this way to prevent moisture and contamination from the outside, so as to maintain the quality of product during distribution / storage. Store at room temperature(≤30℃).

**3) Inner Packaging-polyethylene bag**

**3.1) Specification of Inner Packing Material**

| Item | Standard |
|---|---|
| Appearance | The surface should be smooth and uniform in color, and there should be no perforation, foreign matter, odor, or adhesion.<br>The heat-sealing part of the bag should be flat and free of false sealing. |
| identify | should be consistent with the control pattern |
| Specifications Dimensions | Lenght(mm) 900<br>Width(mm) 600<br>Thickness (mm) 0.08 |
| Microbial limit | The total number of aerobic bacteria≤1000cfu/ml<br>The total number of mold and yeast ≤ 100cfu/ml |

**3.2) Test methods**

**Visual appearance**: The surface should be smooth and uniform in color, and there should be no perforation, foreign matter, odor, or adhesion. The heat-sealing part of the bag should be flat and free of false sealing.

**Identification**: Take 0.25g of the sample (cut into pieces), and reflux the sample with about 10ml of toluene at high temperature to dissolve the sample. The reflux liquid was coated on the potassium bromide wafer with a capillary while it was still hot, and after heating to evaporate the solvent, the infrared spectrum was collected by the transmission method. The infrared spectrum of this product should be consistent with the control spectrum.

**Specifications and dimensions**: use a calibrated ruler to test, the specifications and dimensions of medicinal low-density polyethylene bags should meet the requirements of Table 1

| Check item | Tolerance scope （mm） | | | |
|---|---|---|---|---|
| | Width mm | Long mm | Thick mm | Weight (t)kg |
| Medicinal low density polyethylene bag | 600±5 | 900±5 | 0.08±0.01 | 0.08 |

**Microbial Limit**:

Take 200ml of sterile 0.1% peptone solution, put it into a medicinal low-density polyethylene bag, and shake it up and down 10 times. Take 10ml of the solution and check it according to the "Standard Operating Procedures for Microbial Limit Inspection of Non-sterile products" SOP-012-JYF014, the total number of aerobic bacteria is ≤1000cfu/ml, and the total number of mold and yeast is ≤100cfu/ml.

Appendix 21: Incoming inspection report of plastic bags

**4) External Packaging - Fiber drum**

**4.1) Specification of Fiber drum**

| Test item | Specification |
|---|---|
| Appearance | The paper barrel should be round and free of defects and cracks such as obvious out-of-roundness, concave deflation, skew, etc.<br>The barrel body is smooth, no mechanical damage, no wrinkle, no glue opening. Paint spreads evenly. No paint leakage, no bubbles, no obvious sagging.<br>Round curled edges without paper tongue.<br>Closing and rear lid and barrel body are well sealed, and the barrel body is rolled with imported cardboard paper.<br>The inside and outside of the barrel should be clean, free of impurities and oil stains. |
| Dimensions | Barrel body: 400mm±3mm<br>Inner height: 550mm±3mm<br>Outer height: 570mm±4mm<br>Weight: 3.15±0.3kg |

Appendix 22: Drum Inspection Report