

LeThenea[®] Single-use Freezing Bag

With the rapid development of such industries as clinic application and CAR-T cell therapy, the single-use freezing bags face the double challenges of technology and quality, which further boosts the full upgrade of safety and stability of products as well as supply chain guarantee. LePure adopts the brand-new EVA (ethylene vinyl acetate) tubular film in the current Level C+A clean manufacturing plant, to conduct customized production according to customer's comprehensive needs, rendering high-quality products and professional services for customers.

Typical Applications

It is widely used for cell therapy (such as CAR-T, NK and other cells), freezing/thawing of stem cells (umbilical cord blood stem cells, adipose-derived stem cells and bone marrow stem cells), umbilical cord blood, etc.



Advantages

- Full regulation and control of manufacturing process and quality ensure the product safety and stability
- Long-term contract and storage of raw materials, films and related components meet the guaranteed supplies and delivery reliability
- Perfect study on extractable matters
- Compliance with biosafety requirements
- Airtight integrity test (bacteria & virus)

Product Information

Main connecting parts of the LeThenea® Single-use Freezing Bag can be customized and manufactured according to actual demands of customers

| | | | | | |
|-----------------------------|---|--------|---------|---------|----------|
| Connecting parts | Pipe assembly of freezing tubes (EVA); Luer taper | | | | |
| Port | Injection port*2; Luer taper*3; | | | | |
| Pipe material | EVA (ethylene vinyl acetate) | | | | |
| Specification | 50 mL | 250 mL | 500 mL | 750 mL | 1000 mL |
| Working volume (mL) | 10- 20 | 30- 70 | 55- 100 | 80- 190 | 125- 270 |
| Minimum storage temperature | -196 °C | | | | |
| Thickness | 0.350 mm | | | | |

Technical Parameters

Pharmacopeia Compliance

| Test standard | Test item | Test result |
|---------------|------------------------|-------------|
| USP <661> | Physico-chemical tests | Pass |

Biocompatibility

| Test standard | Test item | Test result |
|---------------|--|-------------|
| ISO 10993-4 | Hemolysis | Pass |
| ISO 10993-5 | Cytotoxicity | Pass |
| ISO 10993-6 | Implantation tests | Pass |
| ISO 10993-10 | Irritation and Sensitization tests | Pass |
| ISO 10993-11 | Acute Systemic Toxicity tests | Pass |
| USP <85> | Bacterial endotoxin tests | Pass |
| USP <87> | Biological reactivity tests, in vitro | Pass |
| USP <88> | Biological reactivity tests, in vivo, class VI | Pass |

Compliance Test

| Test standard | Test item | Test result |
|----------------------------|---------------------------|--------------------|
| Enterprise standard method | Viral impermeability | Pass |
| Enterprise standard method | Freeze-thaw cycles | Pass |
| Enterprise standard method | Pressure resistance | Pass |
| Enterprise standard method | Visible particulate | Pass |
| Enterprise standard method | Integrity tests | Pass |
| Enterprise standard method | Bacterial endotoxin tests | Pass |
| Enterprise standard method | Irradiation tests | Pass |
| USP <788 > | Insoluble particles tests | Pass |
| | | ≥10 μm: ≤10 pcs/mL |
| | | ≥25 μm: ≤1 pcs/mL |
| ASTM F1980-2016 | Expiration Date | two years |

Order Information

LeThenea® Single-use Freezing Bag

| Article No. | Specification | Package |
|-------------|---------------|---------------------------------|
| CR0050-1E | 50 mL | 5 pcs/bag, double-layer package |
| CR0250-1E | 250 mL | 5 pcs/bag, double-layer package |
| CR0500-1E | 500 mL | 5 pcs/bag, double-layer package |
| CR0750-1E | 750 mL | 1 pcs/bag, double-layer package |
| CR001-1E | 1000 mL | 1 pcs/bag, double-layer package |

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