

Specification Sheet

Product No.: 17510500

Product Name: Cellex NK Culture Initial Bag Ver.2

Volume approx.. 10mL

Vessel Resin bag
Main components Buffers

Human proteins Humanized monoclonal antibodies (licensed medicinal product for human use, USP)

Applications Activation of human lymphocytes

Expansion of NK cells with specified protocols

Release specifications:

Osmolality -

pH -

Endotoxin -

Sterility Sterility test of the final product determined according to JP.

Cell culture testing -

Mycoplasma -

Appearance -

Transport +2°C to +8°C. Package with blue ice recommended in ambient temperature.

Storage at +2°C to +8°C. Light protection recommended

Shelf life 4 months from date of production

Intended use For research use only. Not for diagnostic or therapeutic use.

Quality statement

This product is manufactured, tested and released in compliance with ISO 9001

Quality Management Systems. The relevant GMP guidelines have been considered

in the design of this product.



Specification Sheet

Product No.: 16087585

Product Name: Cellex NKGM-1

 $\begin{array}{ccc} Volume & & 1,000 mL \\ Vessel & & PET \ bottle \end{array}$

Main components Salts, Sugars, Amino Acids, Vitamins, Buffers

Contains phenol-red (pH-indicator)

Contains L-glutamine

Human proteins Albumin (human-serum-derived, licensed medicinal product for human use, USP)

Transferrin (human-plasma-derived)

Insulin (human recombinant, yeast-derived)

Applications Cultivation of human lymphocytes

Expansion of NK-cells with specified protocols

Release specifications:

Osmolality 290 ± 15 (mOsm/kg H₂O), determined according to JP.

pH 7.20 ± 0.20 , determined according to JP.

Endotoxin ≤ 0.3 EU/mL, determined according to JP.

Sterility Sterility test of the final product determined according to JP.

Cell culture testing Human lymphocytes proliferation assay

Mycoplasma Real-time PCR assay, according to Ph.Eur.

Appearance Orange-yellow, Clear

Transport +2°C to +8°C. Package with blue ice recommended in ambient temperature.

Storage at +2°C to +8°C. Light protection recommended

Shelf life 8 months from date of production

Intended use For research use only. Not for diagnostic or therapeutic use.

Quality statement

This product is manufactured, tested and released in compliance with ISO 9001

Quality Management Systems. The relevant GMP-guidelines have been considered

in the design of this product.

Human proteins have been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).

Manufacturer



Specification Sheet

Product No.: 16087583

Product Name: Cellex NKGM-Bag

Volume 1,000mL

Vessel EVA bag with tubes

Main components Salts, Sugars, Amino Acids, Vitamins, Buffers

Contains phenol-red (pH-indicator)

Contains L-glutamine

Human proteins Albumin (human-serum-derived, licensed medicinal product for human use, USP)

Transferrin (human-plasma-derived)

Insulin (human recombinant, yeast-derived)

Applications Cultivation of human lymphocytes

Expansion of NK-cells with specified protocols

Release specifications:

Osmolality 290 ± 15 (mOsm/kg H₂O), determined according to JP.

pH 7.20 ± 0.20 , determined according to JP.

Endotoxin ≤ 0.3 EU/mL, determined according to JP.

Sterility Sterility test of the final product determined according to JP.

Cell culture testing Human lymphocytes proliferation assay

Mycoplasma Real-time PCR assay, according to Ph.Eur.

Appearance Orange-yellow, Clear

Transport +2°C to +8°C. Package with blue ice recommended in ambient temperature.

Storage at +2°C to +8°C. Light protection recommended

Shelf life 8 months from date of production

Intended use For research use only. Not for diagnostic or therapeutic use.

Quality statement

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Human proteins have been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).

Manufacturer

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