

GMP CELL CRYOPRESERVATION MEDIA PRODUCT

Nomenclature	Specification	Cat No.	Brief description of use	Expiry date
GMP Cell Cryopreservation Media	100 mL/vial	NC1010	No serum, protein or DMSO The product can be used as the cryopreservation media for cell pharmaceutical excipients	2-8°C, 12 months

NK PURE FACTOR CULTURE SET (FOR PERIPHERAL BLOOD CONCENTRATED WHITE CELLS, CRYOPRESERVED MONOCYTE)

Nomenclature	Specification	Cat No.	Performance description	Expiry date
2 L system	2 vials of NK media (1L) + kit (2L)	NC0102 + AN0102.2	Cell count 5-8 billion, positive rate 50%-90%	12 month
3 L system	3 vials of NK media (1L) + kit (3L)	NC0102 + AN0102.3	Cell count 6-10 billion, positive rate 50%-90%	12 month

NK PURE FACTOR CULTURE SET (FOR UMBILICAL CORD BLOOD)

Nomenclature	Specification	Cat No.	Performance description	Expiry date
2 L system	2 vials of NK media (1L) + kit (2L)	NC0102 + AN0102.2	Cell count 5-8 billion, positive rate 50%-90%	12 month
3 L system	3 vials of NK media (1L) + kit (3L)	NC0102 + AN0102.3	Cell count 6-10 billion, positive rate 50%-90%	12 month

MSC SERUM FREE CULTURE RELATED PRODUCTS

Nomenclature	Cat No.	Specification and storage	Use
MSC Serum Free Basal Medium	NC1010	500 mL/vial Store at 2-8°C Expiry date: 12 months	The product contains rHSA, has no human-derived or animal-derived components, is more suitable for clinical study, and is used for primary separation and follow-up subculturing of umbilical cord and AMSCs. This product can only be used after adding the corresponding medium additives
MSC Serum Free Medium Supplement 1 (Separation of Umbilical Cord-Primary Cells and Construction of Seed Bank)	NC0103.S		This product should be used in conjunction with the MSC serum free basal medium. 500 mL media can be added per 5 mL
MSC Serum Free Medium Supplement 2 (Passage of Umbilical Cord-Cryopreserved Cells and High-Passage Cells)	NC0105.S	500 mL/vial Store at 2-8°C Expiry date: 12 months	This product should be used in conjunction with the MSC serum free basal medium 500 mL media can be added per 5 mL
MSC Serum Free Medium Supplement 3 (Adipose-Primary Cell Separation and Subculturing)	NC0104.S		This product should be used in conjunction with the MSC serum free basal medium 500 mL media can be added per 5 mL
Stem Cell Mild Digestive Enzyme	NC1004.1	500 mL/vial Store at 2-8°C Expiry date: 12 months	It is a gene recombinase, and is expressed in E. coli. It has no human-derived or animal-derived components. It is specially used for passage digestion of stem cell, has mild effect and can avoid over-digestion of stem cells to significantly reduce the culture failure rate of stem cells

YOCON 友康®

GMP CELL CRYOPRESERVATION MEDIA

NMPA Pharmaceutical Excipients Registration No.: F20190000509

Cryopreservation media for cell pharmaceutical excipient



- 1.Safety in line with GMP requirements of pharmaceutical companies
- 2.Toxicity test completed
- 3.Chinese and international patent applications completed
- 4.Traditional cryopreservation media
- 5.GMP cryopreservation media arising with cell drugs

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Product Overview

Use

It is used to store the end-of-production cell drug realize the Recovery In Position (RIP) of cells. In addition, the recovered cells can be directly injected or reinfused to the human body together with the cell cryopreservation media without washing

Features

Traditional cryopreservation media are difficult to be approved to enter the human body with cells since they contain DMSO and protein Or their use may be accompanied by a very high probability of risk

GMP cryopreservation media arising with cell drugs contain no serum, protein or DMSO, and definite components

They can enter the human body along with the cells in the form of pharmaceutical excipients

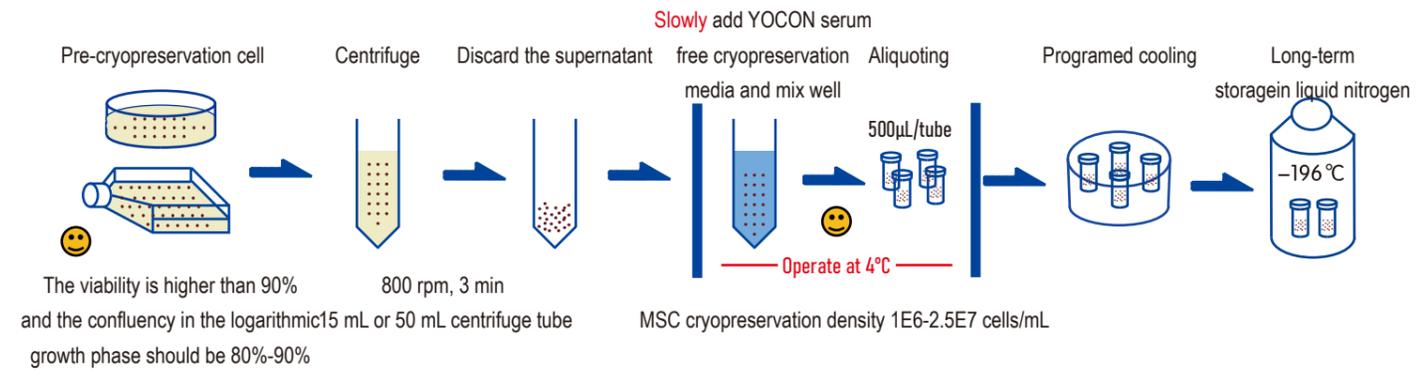
Item	Traditional cell cryopreservation media	GMP Cell Cryopreservation Media
Serum	Present	None
Protein	Present	None
DMSO	Present	None
Endotoxin	>0.25EU/ml	>0.25EU/ml
Programed cooling	Required	Required
Are the components definite	No	Yes
Is it possible to apply for pharmaceutical excipients?	Extremely difficult	Relatively easy

*All uses of "reinfusion into human body" present in this document are premised on that the relevant cell drugs of the pharmaceutical enterprise have obtained the statutory approval by the NMPA. It is only indicated that the product should be able to meet the application requirements based on the performance evaluation. But whether the application is allowed to be used depends solely on the relevant Chinese regulatory authorities. Human testing or application of this product is prohibited without statutory approval.

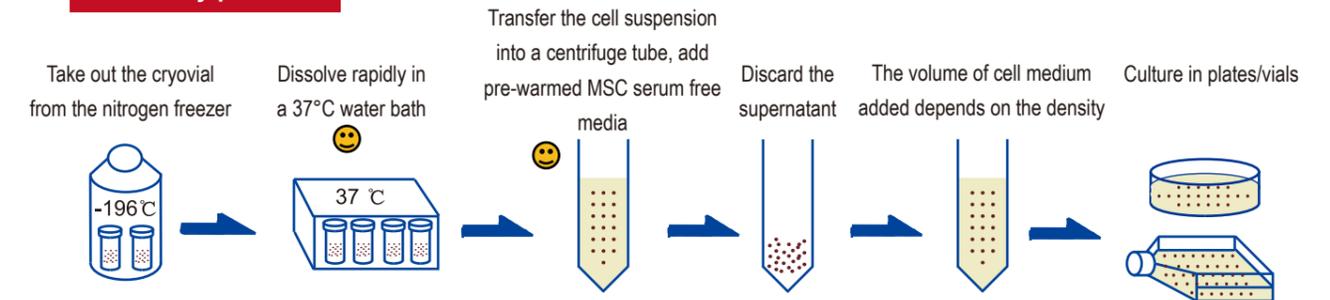
This product as "pharmaceutical excipients" is currently under application and has not yet been approved

Operating process

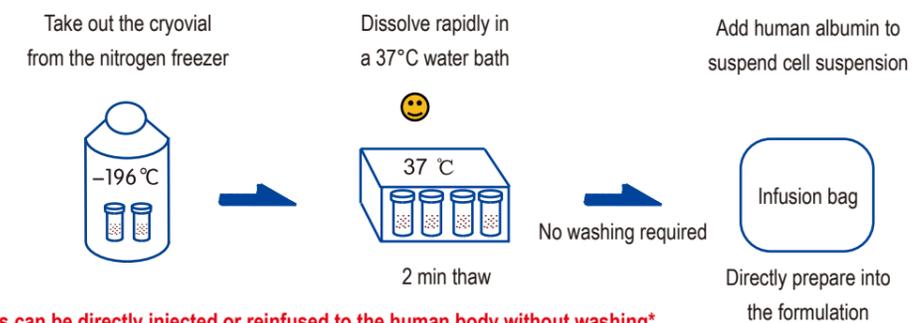
Cryopreservation process



Recovery process



Formulation process



The recovered cells can be directly injected or reinfused to the human body without washing*

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Performance comparison

NK cryopreservation

GMP cell cryopreservation media support high-density (3E7 cells/mL) cryopreservation of NK cells

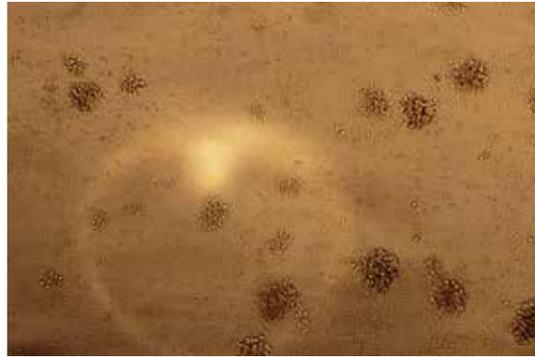


Photo of NK cells stored in the traditional cell cryopreservation media on the day after recovery Cell viability 86%

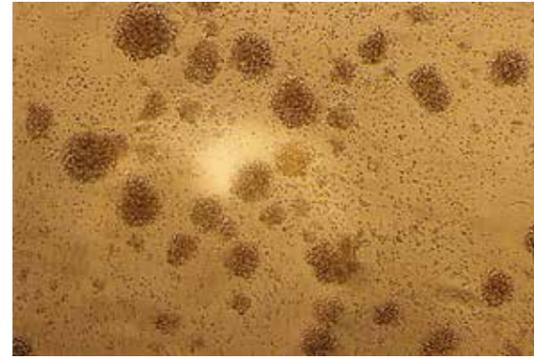
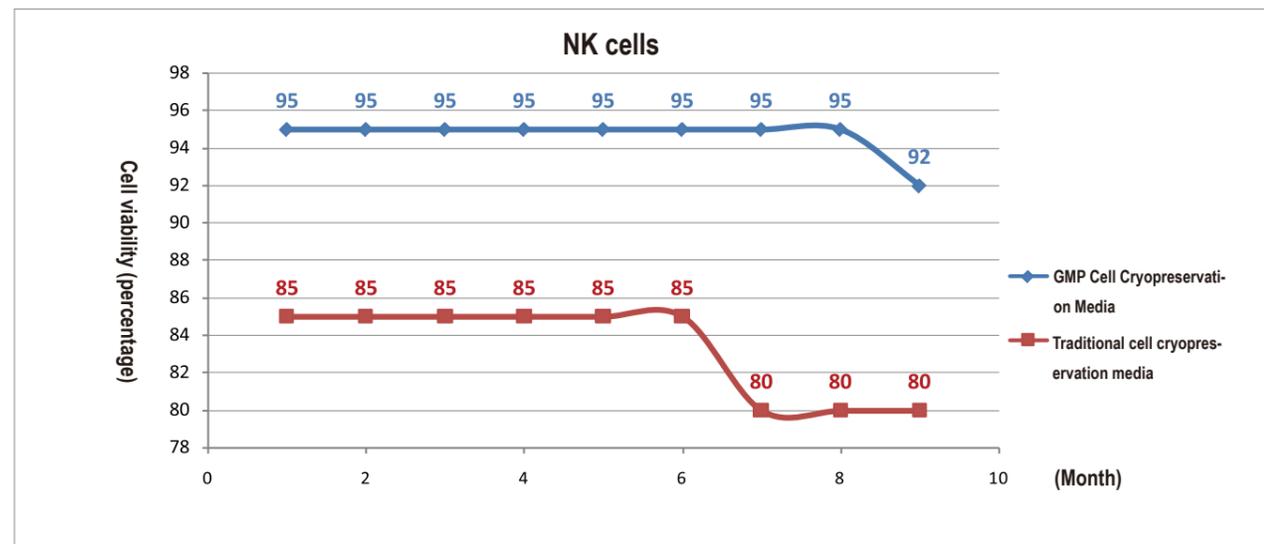


Photo of NK cells stored in the YOCON GMP cell cryopreservation media on the day after recovery Cell viability 96%

Comparison between cryopreservation time and recovery viability (programmed cooling, liquid nitrogen storage)

Cells	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month
NK cells (GMP cell cryopreservation media)	95%	95%	95%	95%	95%	95%	95%	95%	95%
NK cells (traditional cryopreservation media)	85%	85%	85%	85%	85%	85%	85%	85%	85%



Performance comparison

MSC cryopreservation

GMP cell cryopreservation media support high-density (3E7 cells/mL) cryopreservation of NK cells

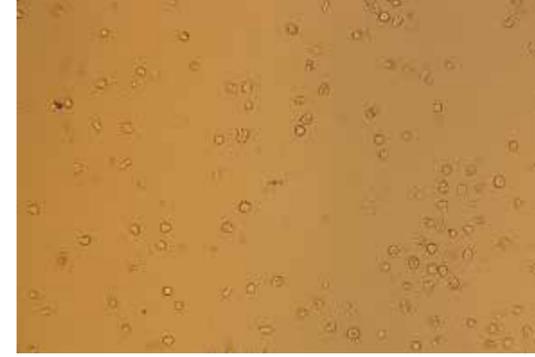


Photo of NK cells stored in the traditional cell cryopreservation media on the day after recovery Cell viability 86%

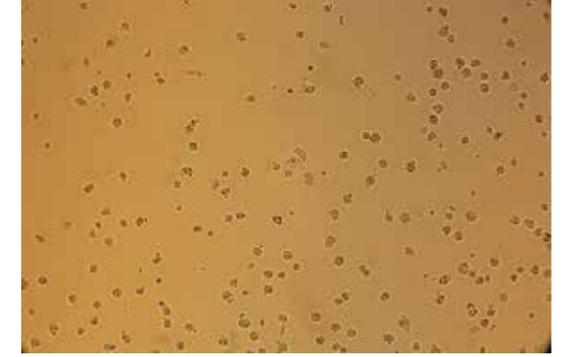
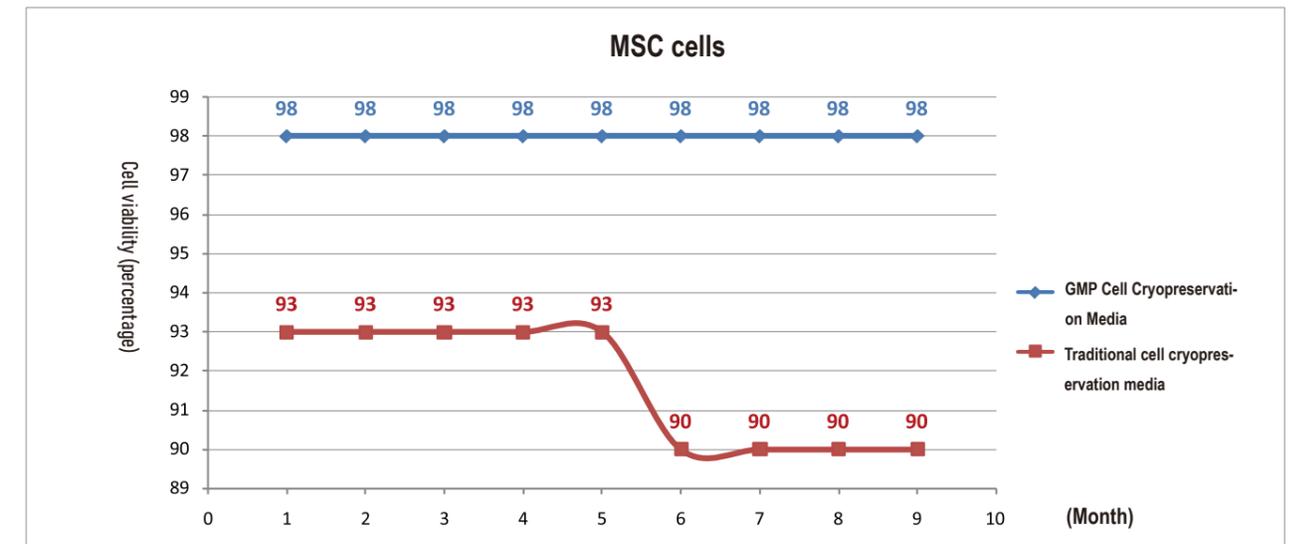


Photo of NK cells stored in the YOCON GMP cell cryopreservation media on the day after recovery Cell viability 96%

Comparison between cryopreservation time and recovery viability (programmed cooling, liquid nitrogen storage)

Cells	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month
Umbilical cord MSC (GMP cell cryopreservation media)	98%	98%	98%	98%	98%	98%	98%	98%	98%
Umbilical cord MSC (traditional cryopreservation media)	93%	93%	93%	93%	93%	90%	90%	90%	90%



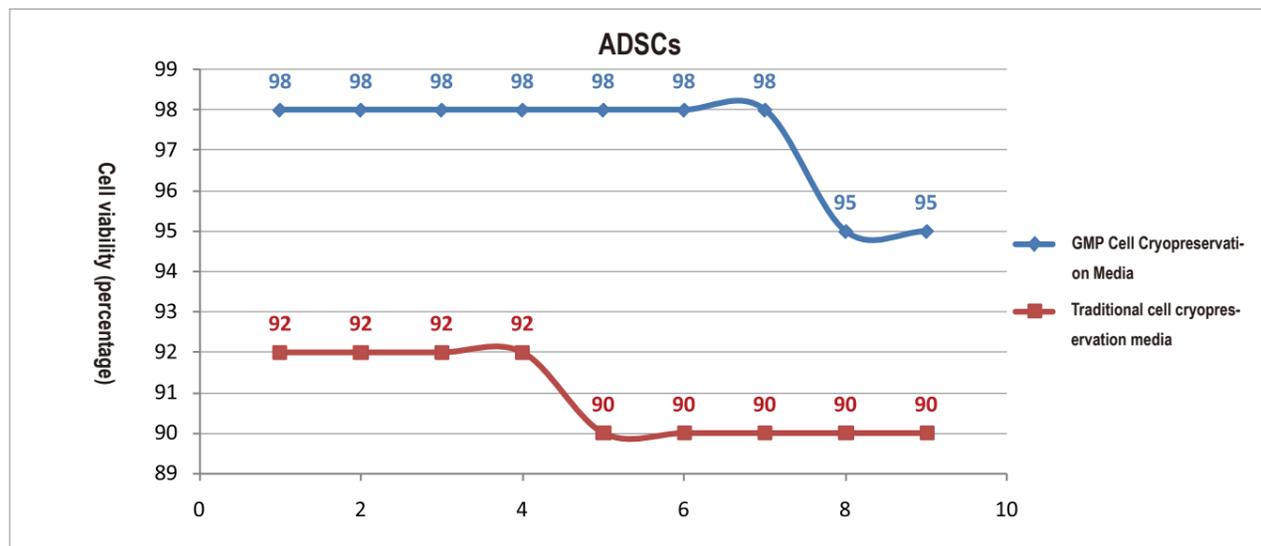
ADSC cryopreservation

The primary ADSCs separated and grown in serum free media are cryopreserved in liquid nitrogen with Yocon GMP cell cryopreservation media. The ADSCs are recovered in ADSC serum free media for 72 hours, and then serially passaged, as shown in the figure:



Comparison between cryopreservation time and recovery viability (programmed cooling, liquid nitrogen storage)

Cells	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month
ADSCs (GMP cell cryopreservation media)	98%	98%	98%	98%	98%	98%	98%	95%	95%
ADSCs (traditional cryopreservation media)	92%	92%	92%	92%	90%	90%	90%	90%	90%



Safety in line with GMP requirements

No serum, protein or DMSO, and definite components The media are suitable for cell drug application of cell formulation enterprises

Test item: Acute systemic toxicity

Test method: YBB00042003-2015 Acute Systemic Toxicity Test

Test result: In the 72-hour observation phase, the mice in both the control group and the test group had no abnormal reaction, no death, and normal weight gain.

Test conclusion: The 1:50 diluent of this product was tested according to the YBB00042003-2015 Acute Systemic Toxicity Test, and the test results were determined to be qualified.

