GMP N-2 MAX Media Supplement (100X), Animal Free

Animal-free Media Supplement for *Ex Vivo* Cell or Tissue Manufacturing

Catalog Number: AR016

Volume: 5 mL

PRODUCT DESCRIPTION

GMP N-2 MAX Media Supplement is manufactured using animal-free raw materials in an animal-free laboratory following cGMP guidelines. This media supplement can be added to base media formulations to support the expansion of neural stem cells (1) under cGMP-grade culture conditions. GMP N-2 MAX Media Supplement has been modified from the Bottenstein's formulation (2) to be compliant in *ex vivo* cell and tissue manufacturing work flows. It is supplied as a 100X concentrate.

STABILITY & STORAGE

Product is shipped on dry ice. Store **in the dark** at ≤ -20 °C in a manual defrost freezer. Do not use beyond the expiration date.

MEDIA SUPPLEMENT COMPONENTS

COMPONENT	AMOUNT (µg/mL)
Recombinant Human Insulin	2500
Recombinant Human Transferrin	10,000
Putrescine	1611
Selenite	0.52
Progesterone	0.63

PRODUCT TESTING

TEST	SPECIFICATION
Endotoxin Level	≤ 2 EU/mL for a 1X solution.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
Sterility	Tested to USP <71> sterility guidelines.
Activity	Supports expansion and maintained multipotency of undifferentiated rat cortical stem cells over 3 passages in culture.

SAFETY INFORMATION

- For use in preclinical research or for *ex vivo* cell and tissue manufacturing.
- Not intended for direct administration into humans or animals. Not for parenteral use.
- The safety and efficacy of this product in diagnostic or other clinical uses has not been established.

PRECAUTION

When handling bio-hazardous materials such as human cells, safe laboratory procedures should be followed and protective clothing should be worn.

LIMITATIONS

- This reagent should not be used beyond the expiration date indicated on the label.
- Do not use if package is damaged. Use undamaged and sealed bottles only.
- Results may vary due to variations among cells derived from different donors.

MEDIA PREPARATION

Dilute GMP N-2 MAX Media Supplement 1:100 in basal media before use. The diluted medium may be stored **in the dark** at 2-8 °C for up to 2 weeks. **Note:** *For ex vivo cell or tissue manufacturing applications, this supplement should be used in combination with GMP-compliant base media and raw materials.*

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MANUFACTURING SPECIFICATIONS

R&D Systems® GMP media is produced according to relevant sections of the following documents: WHO TRS, No. 822,1992 Annex 1, Good Manufacturing Practices for Biological Products and USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue Engineered Products.

R&D Systems® quality focus includes:

- Manufacturing and testing under an ISO 9001:2015 and ISO 13485:2016 certified quality system.
- Documented processes and QA control of documentation and process changes.
- Personnel training programs.
- Raw material testing and vendor qualification/monitoring.
- Fully validated equipment, processes and test methods.
- Equipment calibration schedules using a computerized calibration program.
- Facility maintenance, safety programs and pest control.
- Material review process for variances.
- Monitoring of stability over product shelf life.

Additional testing and documentation requested by the customer can be arranged at an additional cost.

Production records and facilities are available for examination by appropriate personnel on site at R&D Systems® in Minneapolis, Minnesota USA.

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REFERENCES

1. Johe, K.K. *et al.* (1996) Genes & Development **10**:3129.
2. Bottenstein, J.E. (1985) Cell Culture in the Neurosciences, Plenum Press: New York and London.