Certificate of Analysis



Cellartis® DEF-CS™ 500 Xeno-Free GMP Grade Basal Medium

Catalog No. Y30071

Amount 500 ml

Lot Number AJXL019

Description

Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium is a chemically defined basal media that is free from human- and animal-derived components and is used for efficient expansion of undifferentiated human induced pluripotent stem (iPS) cells. Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium is manufactured as a quality-assured product, according to guidelines for Good Manufacturing Practice (GMP) for Medicinal Products.

Package Contents

• 1 bottle Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium (500 ml)

Storage Conditions

• Store at 2–8°C

Shelf Life

Specified on product label

Shipping Conditions

• 2-8°C

Product Documents

Documents for Takara Bio Europe AB products are available for download at www.takarabio.com/manuals
The following documents apply to this product:

• Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium User Manual

Quality Control Data

Test Item	Specifications	Results	
1) Sterility Testing	Negative	Negative	
2) Mycoplasma Testing	Negative	Negative	
3) pH	7.4 ± 0.2	7.3	
4) Endotoxin Testing	< 5.0 EU/ml	< 0.1 EU/ml	
5) Osmolality	$315 \pm 15 \text{ mOsm/kg}$	310-311 mOsm/kg	

Quality Statements

- Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium is manufactured and tested in compliance with applicable parts of PIC/S PE 009-14 "Guide to Good Manufacturing Practice for Medicinal Products".
- This medium contains no animal- or human-derived components.

Certificate of Analysis

Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium

It is certified that this product meets the above specifications.

Approved by:

Quality Assurance

Date: DD-Month-YYYY

Takara Bio Europe AB

Notice to Purchaser

This product is to be used for Research Use or non-commercial manufacturing for clinical research. This product is not intended for human or animal in vivo applications. Our products may not be transferred to third parties, resold, modified for resale, or used to manufacture commercial products or to provide a service to third parties without our prior written approval.

If you require licenses for other use, please contact us by phone at +46.(0)31.758.0900.

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