

Certificate of Analysis

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

Catalog No.
Y30071

Amount
500 ml

Lot Number
AI6L017

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 Investigational 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

- Blue ice (2-8°C)

Product Documents

Documents for Takara Bio Europe AB products are available for download at www.takarabio.com/manuals

The following document applies 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	7.4
4) Endotoxin Testing	< 5.0 EU/ml	1.0 EU/ml
5) Osmolality	315 ± 15 mOsm/kg	310-311 mOsm/kg

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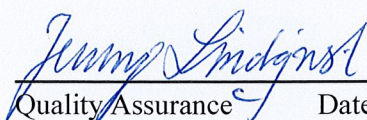
Cellartis® DEF-CS™ 500 Xeno-Free GMP Grade Basal Medium

Quality Statements

- Cellartis® DEF-CS™ 500 Xeno-Free GMP Grade Basal Medium is manufactured and tested in accordance with the following guidelines; “Standards for Manufacturing Control and Quality Control, etc. of Investigational Products (Investigational products GMP)” notified by Ministry of Health and Welfare Japan (“PFSB Notification No. 0709002, July 9, 2008)” (PFSB: Pharmaceutical and Food Safety Bureau).
- This medium contains no animal- or human-derived components.

It is certified that this product meets the above specifications.

Approved by:



Quality Assurance

Date: 17-Sep-2018

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 31 758 0900.

Your use of this product is also subject to compliance with any applicable licensing requirements as detailed below, in our catalogues, on our website at <http://www.takarabio.com>, on the label or other documentation accompanying the goods. It is your responsibility to review, understand and adhere to any restrictions imposed by such statements.

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This document has been reviewed and approved by the Takara Bio Europe AB Quality Assurance Department.